

(h) Exceptions to TCCA AD CF-2020-41

(1) Where TCCA AD CF-2020-41 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph A. of TCCA AD CF-2020-41 requires amending the existing airplane flight manual (AFM) by “incorporating the SUPPLEMENT 21 Operation above 29000 feet from AFM Revision 15-A dated 10 September 2020,” this AD requires amending the existing AFM by incorporating Supplement 21—Operation Above 29000 Feet, of Airbus A220-100 Airplane Flight Manual, Publication BD500-3AB48-22200-00, and Airbus A220-300 Airplane Flight Manual Publication BD500-3AB48-32200-00, both Issue 016, dated October 16, 2020.

(3) Where paragraph A. of TCCA AD CF-2020-41 specifies to “[i]nform all flight crews of the new supplement and thereafter operate the aeroplane accordingly,” this AD does not require those actions as those actions are already required by existing FAA operating regulations.

(4) Where paragraphs B. and C. of TCCA AD CF-2020-41 specify procedures for a borescope inspection for signs of damage of the 1st stage axial low-pressure compressor (LPC) rotor of each engine, to be performed after the AFM N1 limitation has been exceeded, this AD does not require that action.

(5) Where paragraph C. of TCCA AD CF-2020-41 describes an optional installation of health management unit reports to monitor N1 exceedances, this AD does not include that option.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7300; fax 516-794-5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or TCCA; or Airbus Canada Limited Partnership's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

For more information about this AD, contact Thomas Niczky, Aerospace Engineer,

Avionics and Electrical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7347; fax 516-794-5531; email 9-avs-nyaco-cos@faa.gov.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Supplement 21—Operation Above 29000 Feet, of Airbus A220-100 Airplane Flight Manual, Publication BD500-3AB48-22200-00, Issue 016, dated October 16, 2020.

(ii) Supplement 21—Operation Above 29000 Feet, of Airbus A220-300 Airplane Flight Manual Publication BD500-3AB48-32200-00, Issue 016, dated October 16, 2020.

(iii) Transport Canada Civil Aviation (TCCA) AD CF-2020-41, issued October 15, 2020.

(3) For TCCA AD CF-2020-41, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario, K1A 0N5, CANADA; telephone 888-663-3639; email AD-CN@tc.gc.ca; internet <https://tc.canada.ca/en/aviation>.

(4) For Airbus service information identified in this AD, contact Airbus Canada Limited Partnership, 13100 Henri-Fabre Boulevard, Mirabel, Québec J7N 3C6, Canada; telephone 450-476-7676; email a220_crc@abc.airbus; internet <https://a220world.airbus.com>.

(5) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195. This material may be found in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0269.

(6) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on July 30, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

Note: This document was received for publication by the Office of the Federal Register on December 14, 2021.

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DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Part 744**

[Docket No. 211213-0259]

RIN 0694-A168

Addition of Certain Entities to the Entity List and Revision of an Entry on the Entity List

AGENCY: Bureau of Industry and Security, Commerce

ACTION: Final rule.

SUMMARY: This final rule amends the Export Administration Regulations (EAR) by adding thirty-seven entities under forty entries to the Entity List. These thirty-seven entities have been determined by the U.S. Government to be acting contrary to the foreign policy or national security interests of the United States and will be listed on the Entity List under the destinations of the People's Republic of China (China), Georgia, Malaysia, and Turkey. This final rule also modifies one existing entry on the Entity List under the destination of China.

DATES: This rule is effective December 17, 2021.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary for Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482-5991, Email: ERC@bis.doc.gov.

SUPPLEMENTARY INFORMATION:**Background***Entity List*

The Entity List (supplement no. 4 to part 744 of the EAR) identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entities have been involved, are involved, or pose a significant risk of being or becoming involved in activities contrary to the national security or foreign policy interests of the United States. The EAR (15 CFR parts 730-774) impose additional license requirements on, and limit the availability of most license exceptions for, exports, reexports, and transfers (in-country) to listed entities. The license review policy for each listed entity is identified in the “License Review Policy” column on the Entity List, and the impact on the availability of license exceptions is described in the relevant **Federal Register** document adding entities to the Entity List. BIS places entities on the Entity List

pursuant to part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and makes all decisions to remove or modify an entry by unanimous vote.

ERC Entity List Decisions

Additions to the Entity List

This rule implements the decision of the ERC to add thirty-seven entities under forty entries to the Entity List. The thirty-seven entities are added based on § 744.11 (License requirements that apply to entities acting contrary to the national security or foreign policy interests of the United States) of the EAR. The entities are located in the People's Republic of China (China), Georgia, Malaysia, and Turkey. Of the forty entries, thirty-four are located in China, three are located in Georgia, one is located in Malaysia, and two are located in Turkey. Three entities are listed under multiple destinations, accounting for the difference between the number of entities and number of entries in this final rule.

The ERC determined to add the Academy of Military Medical Sciences (AMMS) in China and eleven of its research institutes (the Institute of Health Service and Medical Information; the Institute of Radiation and Radiation Medicine; the Institute of Basic Medicine; the Institute of Hygiene and Environmental Medicine; the Institute of Microbiology and Epidemiology; the Institute of Toxicology and Pharmacology; the Institute of Medical Equipment; the Institute of Bioengineering; the Field Blood Transfusion Institute; the Institute of Disease Control and Prevention; and the Military Veterinary Research Institute) to the Entity List under the destination of China based on the body of information that AMMS and its eleven research institutes use biotechnology processes to support Chinese military end uses and end users, to include purported brain-control weaponry. This activity is contrary to U.S. national security and foreign policy interests under § 744.11(b) of the EAR.

The ERC determined to add China Electronics Technology Group

Corporation 52nd Research Institute, Shaanxi Reactor Microelectronics Co. Ltd., Shanghai AisinoChip Electronics Co., Ltd., and Hangzhou Hikmicro Sensing Technology Co., Ltd. to the Entity List for their support of China's military modernization. This activity is contrary to national security and foreign policy interests under Section 744.11(b) of the EAR. In addition, the ERC determined to add HMN International, Jiangsu Hengtong Marine Cable Systems, Jiangsu Hengtong Optic-Electric, Shanghai Aoshi Control Technology Co., Ltd., and Zhongtian Technology Submarine Cable to the Entity List for acquiring and attempting to acquire U.S.-origin items in support of military modernization for the People's Liberation Army. This activity is contrary to national security and foreign policy interests under Section 744.11(b) of the EAR.

As determined by the ERC, Wavelet Electronics, Comtel Technology Limited, and HSJ Electronics are being added to the Entity List under the destination of China for actions contrary to the national security or foreign policy interests of the United States. Specifically, these companies have supplied or attempted to supply U.S.-origin items that could provide material support to Iran's advanced conventional weapons and missile programs to entities designated by the U.S. Department of the Treasury's Office of Foreign Assets Control as Specially Designated Nationals (SDN).

The ERC determined to add Aeroson Corporation, Changsha Jingjia Microelectronics Co., Ltd., Fujian Torch Electron Technology Co., Ltd., and Inner Mongolia First Machinery Group Co., Ltd. to the Entity List for their support of China's military modernization. This activity is contrary to national security and foreign policy interests under Section 744.11(b) of the EAR.

The ERC determined to add the following entities to the Entity List for their involvement in activities that are contrary to the national security and/or foreign policy interests of the United States: Hong Kong Cheung Wah Electronics Technology Company Limited, Hyper Systems Union Limited, Shenzhen Rion Technology, and Thundsea Electric Limited, under the destination of China; Gensis Engineering under the destinations of Georgia and Turkey; Integrated Scientific Microwave Technology under the destinations of China and Malaysia; ROV Solutions under the destinations of China and Georgia; SAEROS Safety ERO Company under the destination of Georgia; and Vangurd Tec Makina Sanyit Ithalat under the destination of Turkey.

Specifically, these entities are a part of a network used to supply or attempt to supply Iran with U.S.-origin items that would ultimately provide material support to Iran's defense industries, in violation of U.S. export controls.

Pursuant to § 744.11(b) of the EAR, the ERC determined that the conduct of the above-described entities raises sufficient concerns that prior review, via the imposition of a license requirement for exports, reexports, or transfers (in-country) of all items subject to the EAR involving these thirty-seven entities and the possible issuance of license denials or the possible imposition of license conditions on shipments to these entities, will enhance BIS's ability to prevent violations of the EAR or otherwise protect U.S. national security or foreign policy interests.

For the entities added to the Entity List in this final rule, BIS imposes a license requirement that applies to all items subject to the EAR. In addition, no license exceptions are available for exports, reexports, or transfers (in-country) to the persons being added to the Entity List in this rule. For all entities being added to the Entity List, BIS imposes a license review policy of a presumption of denial. The acronym "a.k.a.," which is an abbreviation of 'also known as,' is used in entries on the Entity List to identify aliases, thereby assisting exporters, reexporters and transferors in identifying entities on the Entity List.

For the reasons described above, this final rule adds the following thirty-seven entities under forty entries to the Entity List and includes, where appropriate, aliases:

China

- Academy of Military Medical Sciences;
- Academy of Military Medical Sciences, Field Blood Transfusion Institution;
- Academy of Military Medical Sciences, Institute of Basic Medicine;
- Academy of Military Medical Sciences, Institute of Bioengineering;
- Academy of Military Medical Sciences, Institute of Disease Control and Prevention;
- Academy of Military Medical Sciences, Institute of Health Service and Medical Information;
- Academy of Military Medical Sciences, Institute of Hygiene and Environmental Medicine;
- Academy of Military Medical Sciences, Institute of Medical Equipment;
- Academy of Military Medical Sciences, Institute of Microbiology and Epidemiology;

- Academy of Military Medical Sciences, Institute of Radiation and Radiation Medicine;
- Academy of Military Medical Sciences, Institute of Toxicology and Pharmacology;
- Academy of Military Medical Sciences, Military Veterinary Research Institute;
- Aerosun Corporation;
- Changsha Jingjia Microelectronics Co., Ltd.;
- China Electronics Technology Group Corporation 52nd Research Institute;
- Comtel Technology Limited;
- Fujian Torch Electron Technology Co., Ltd.;
- Hangzhou Hikmicro Sensing Technology Co., Ltd.;
- HMN International Co., Ltd.;
- Hong Kong Cheung Wah Electronics Technology Company Limited;
- HSJ Electronics;
- Hyper Systems Union Limited;
- Inner Mongolia First Machinery Group Co., Ltd.;
- Integrated Scientific Microwave Technology;
- Jiangsu Hengtong Marine Cable Systems Co., Ltd.;
- Jiangsu Hengtong Optic-Electric Co., Ltd.;
- ROV Solutions;
- Shaanxi Reactor Microelectronics Co., Ltd.;
- Shanghai Aisinochip Electronics Technology Co., Ltd.;
- Shanghai Aoshi Control Technology Co., Ltd.;
- Shenzhen Rion Technology;
- Thundsea Electric Limited;
- Wavelet Electronics; *and*
- Zhongtian Technology Submarine Cable Co.

Georgia

- Gensis Engineering;
- ROV Solutions, *and*
- SAEROS Safety ERO Company.

Malaysia

- Integrated Scientific Microwave Technology.

Turkey

- Gensis Engineering; *and*
- Vangurd Tec Makina Sanyi Ithalat.

Revisions of Entity on the Entity List

The ERC determined to modify one existing entry on the Entity List, Huawei Technologies Co., Ltd. (Huawei), first added to the Entity list under the destination of China on May 2019 (84 FR 22963). Specifically, this rule adds three additional aliases (HMN Technologies, Huahai Zhihui Technology Co., Ltd., and HMN Tech)

under one of its affiliated entities: Huawei Marine Networks.

Savings Clause

Shipments of items removed from eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on December 17, 2021, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR).

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications and commodity classification, and carries a burden estimate of 29.6 minutes for a manual or

electronic submission for a total burden estimate of 31,835 hours. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to § 1762 of the Export Control Reform Act of 2018, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for 15 CFR part 744 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 15, 2021, 86 FR 52069 (September 17, 2021); Notice of November 10, 2021, 86 FR 62891 (November 12, 2021).2.

■ 2. Supplement No. 4 to part 744 is amended:

■ a. Under CHINA, PEOPLE'S REPUBLIC OF:

■ i. By adding in alphabetical order entries for “Academy of Military Medical Sciences,” “Academy of Military Medical Sciences, Field Blood Transfusion Institution,” “Academy of Military Medical Sciences, Institute of Basic Medicine,” “Academy of Military Medical Sciences, Institute of Bioengineering,” “Academy of Military Medical Sciences, Institute of Disease

Control and Prevention,” “Academy of Military Medical Sciences, Institute of Health Service and Medical Information,” “Academy of Military Medical Sciences, Institute of Hygiene and Environmental Medicine,” “Academy of Military Medical Sciences, Institute of Medical Equipment,” “Academy of Military Medical Sciences, Institute of Microbiology and Epidemiology,” “Academy of Military Medical Sciences, Institute of Radiation and Radiation Medicine,” “Academy of Military Medical Sciences, Institute of Toxicology and Pharmacology,” “Academy of Military Medical Sciences, Military Veterinary Research Institute,” “Aerosun Corporation,” “Changsha Jingjia Microelectronics Co., Ltd.,” “China Electronics Technology Group Corporation 52nd Research Institute,” “Comtel Technology Limited,” “Fujian

Torch Electron Technology Co., Ltd.,” “Hangzhou Hikmicro Sensing Technology Co., Ltd.,” “HMN International Co., Ltd.”; “Hong Kong Cheung Wah Electronics Technology Company Limited,” and “HSJ Electronics”;
 ■ ii. By revising the entry for “Huawei Technologies”; and
 ■ iii. By adding in alphabetical order entries for “Hyper Systems Union Limited,” “Inner Mongolia First Machinery Group Co., Ltd.,” “Integrated Scientific Microwave Technology,” “Jiangsu Hengtong Marine Cable Systems Co., Ltd.,” “Jiangsu Hengtong Optic-Electric Co., Ltd.,” “ROV Solutions,” “Shaanxi Reactor Microelectronics Co., Ltd.,” “Shanghai Aisinochip Electronics Technology Co., Ltd.,” “Shanghai Aoshi Control Technology Co., Ltd.,” “Shenzhen Rion

Technology,” “Thundsea Electric Limited,” “Wavelet Electronics,” and “Zhongtian Technology Submarine Cable Co.”;
 ■ b. Under GEORGIA, by adding in alphabetical order, entries for “Gensis Engineering,” “ROV Solutions,” and “SAEROS Safety ERO Company”;
 ■ c. Under MALAYSIA, by adding in alphabetical order, an entry for “Integrated Scientific Microwave Technology”; and
 ■ d. Under TURKEY, by adding in alphabetical order, entries for “Gensis Engineering” and “Vangurd Tec Makina Sanyi Ithalat”.
 The additions and revision read as follows:

Supplement No. 4 to Part 744—Entity List

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Country	Entity	License requirement	License review policy	Federal Register citation
*	*	*	*	*
CHINA, PEOPLE'S REPUBLIC OF.				
	Academy of Military Medical Sciences, a.k.a., the following one alias: —AMMS. 27 Taiping Road, Haidian District, Beijing, 100850, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
	Academy of Military Medical Sciences, Field Blood Transfusion Institution, 27 Taiping Road, Haidian District, Beijing, 100850, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
	Academy of Military Medical Sciences, Institute of Basic Medicine, 27 Taiping Road, Haidian District, Beijing, 100850, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
	Academy of Military Medical Sciences, Institute of Bioengineering, 20 East Street, Fengtai District, Beijing, China 100071.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
	Academy of Military Medical Sciences, Institute of Disease Control and Prevention, a.k.a., the following one alias: —Disease Control and Prevention Institute. 20 East Street, Fengtai District, Beijing, China 100071.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
	Academy of Military Medical Sciences, Institute of Health Service and Medical Information, 27 Taiping Road, Haidian District, Beijing, 100850, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
	Academy of Military Medical Sciences, Institute of Hygiene and Environmental Medicine, No. 1 Dali Road, Heping District, Tianjin, 300050, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
	Academy of Military Medical Sciences, Institute of Medical Equipment, 106 Wandong Road, Hedong District, Tianjin, 300162, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].

Country	Entity	License requirement	License review policy	Federal Register citation
	Academy of Military Medical Sciences, Institute of Microbiology and Epidemiology, a.k.a, the following one alias: —Institute of Microbial Epidemiology. 20 East Street, Fengtai District, Beijing, 100071, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
	Academy of Military Medical Sciences, Institute of Radiation and Radiation Medicine, a.k.a., the following two aliases: —Institute of Radiation Medicine; <i>and</i> —Institute of Electromagnetic and Particle Radiation Medicine. 27 Taiping Road, Haidian District, Beijing, 100850, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
	Academy of Military Medical Sciences, Institute of Toxicology and Pharmacology, a.k.a., the following one alias: —Institute of Toxicology and Drugs. 27 Taiping Road, Haidian District, Beijing, 100850, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
	Academy of Military Medical Sciences, Military Veterinary Research Institute, 666 Liuying West Road, Changchun City, 130122, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Aerosun Corporation, No. 188, Tianyuan Middle Road, Jiangning Economic and Technological Development Zone, Nanjing City, Jiangsu Province 211100; <i>and</i> 188 Tianyuan Zhong Road, Jiangning Economic & Technical Area Nanjing, Jiangsu 211100; <i>and</i> No. 3931, Chuansha Road, Wanggang Town, Pudong New Area, Chuansha County, Shanghai 201201; <i>and</i> Building 1, No. 199 Jiangjun Avenue, Jiangning Economic and Technological Development Zone, Nanjing; <i>and</i> No. 9399 Shangchuan Road, South District, Jinqiao Processing Zone, Pudong New District, Shanghai, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Changsha Jingjia Microelectronics Co., Ltd., 902, Building B1, Lugu Science and Technology Innovation Pioneer Park, 1698 Yuelu West Ave., Changsha High-tech Development Zone; <i>and</i> Building 3, Changsha Productivity Promotion Center, No. 2, Lujing Rd., Yuelu District, Changsha City, Hunan Province; <i>and</i> No. 1, Meixihu Road, Yuelu District, Changsha City, Hunan Province, 410221; <i>and</i> Room 1501, Aipu Building, 395 Xinshi North Road, Shijiazhuang City, Hebei Province, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	China Electronics Technology Group Corporation 52nd Research Institute, a.k.a., the following three aliases: —CETC 52; —CETHIK Group; <i>and</i> —China Electronics Technology HIK Group Co., Ltd.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].

Country	Entity	License requirement	License review policy	Federal Register citation
	198 Aicheng Street, Wuchang Avenue, Yuhang District, Hangzhou; <i>and</i> No. 36, Macheng Road, Xihu District, Hangzhou; <i>and</i> No. 1500, Wenyi West Road, Yuhang District; <i>and</i> No. 9 Lixin Road Qingha Lake, Hangzhou; <i>and</i> No. 9 Wenfu Road, Hangzhou, China.			
	* * *			
	Comtel Technology Limited, Building A2-3, Haufeng Industrial Park, Shiyao, Baoan District, Shenzhen, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Fujian Torch Electron Technology Co., Ltd., No.4 Zihua Rd., Quanzhou Hi-Tech Industries Park (Jiang Nan Park) Licheng District, Quanzhou, Fujian; <i>and</i> Building 23, District 7, No. 188 South 4th Ring Rd W, Fengtai District, Beijing; <i>and</i> Suites 705-708, 7th floor, Ping'An Wealth Management Center, Building 1, 1588 Shenchang Road, Minhang District, Shanghai; <i>and</i> Suites 2904-2905, Yongwei Times Center, Jinye 1st Rd, Yanta District, Xi'an; <i>and</i> Suites 402-1, Building 1, Xicun Compound, No 1. Beisen N Rd, Qingyang District, Chengdu; <i>and</i> Suite 1507, Tower A, Wuhan Guanggu Times Square, No. 111 Guanshan Avenue Hongshan District, Wuhan; <i>and</i> Suite 905, Kairu Junlin Business Building, Intersection of Kaixuan W Rd and Shachang S Rd, Xigong District, Luoyang; <i>and</i> Suite 2306, Tower A, YINUO Business Center, Intersection of West 2nd Ring Rd and Hehuan Road, Shushan District, Hefei; <i>and</i> Suite 404, Building W2, West District, Airport Business Park, Tianjin Airport Economic Zone; <i>and</i> Suites 1102-1103, Tower B2, No. 13 Ludu Avenue, Greenland Window Business Plaza, Yuhuatai District, Nanjing; <i>and</i> Suite 10009, Times Building, No. 55 Qingjiang Rd, Weibin District, Baoji, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Hangzhou Hikmicro Sensing Technology Co., Ltd., a.k.a., the following one alias: —Hikmicro. Building A1, No. 299, Qiushi Road, Tonglu Economic Development Zone, Tonglu County, Hangzhou City, Zhejiang Province; <i>and</i> No. 209 Gold Road, Fuyang District Hangzhou, Zhejiang; <i>and</i> Fuyang Branch—1st Floor, Building 4, No. 209, Golf Road, Dongzhou St., Fuyang District, Hangzhou City, Zhejiang province, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
	* * *			
	HMN International Co., Ltd., a.k.a. the following one alias: —Huahai Communication International Co., Ltd. Room 08, 43/F., Far East Finance Centre, No. 16 Harcourt Road, Admiralty, Hong Kong.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].

Country	Entity	License requirement	License review policy	Federal Register citation
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	Hong Kong Cheung Wah Electronics Technology Company Limited, Flat D, 14/F., On Fook Ind. Bldg. 41–45 Kwai Fung Crescent, Kwai Chung, N.T., Hong Kong; <i>and</i> Room 2307, Dynamic World Bldg., Zhenzhong Road, Futian District, Shenzhen, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	HSJ Electronics, a.k.a., the following one alias: —HSJ Electronic Hong Kong Limited. Room 803, Chevalier House 45–51, Chatham Road South, Tsim Sha Tsui, Hong Kong; <i>and</i> 10/F Kras Asia Industrial Building 79 Hung to Road, Kowloon, Hong Kong.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Huawei Technologies Co., Ltd., a.k.a., the following two aliases: —Shenzhen Huawei Technologies; <i>and</i> —Huawei Technology, and to include the following addresses and the following 22 affiliated entities: Addresses for Huawei Technologies Co., Ltd.: Bantian Huawei Base, Longgang District, Shenzhen, 518129, China; <i>and</i> No. 1899 Xi Yuan Road, High-Tech West District, Chengdu, 611731; <i>and</i> C1, Wuhan Future City, No. 999 Gaoxin Ave., Wuhan, Hebei Province; <i>and</i> Banxuegang Industrial Park, Buji Longgang, Shenzhen, Guangdong, 518129, China; <i>and</i> R&D Center, No. 2222, Golden Bridge Road, Pu Dong District, Shanghai, China; <i>and</i> Zone G, Huawei Base, Bantian, Longgang District, Shenzhen, China. Affiliated entities: <i>Beijing Huawei Longshine Information Technology Co., Ltd.</i> , a.k.a., the following one alias: —Beijing Huawei Longshine, to include the following subordinate. Q80–3–25R, 3rd Floor, No. 3, Shangdi Information Road, Haidian District, Beijing, China. <i>Hangzhou New Longshine Information Technology Co., Ltd.</i> , Room 605, No. 21, Xinba, Xiachang District, Hangzhou, China. <i>Hangzhou Huawei Communication Technology Co., Ltd.</i> , Building 1, No. 410, Jianghong Road, Changhe Street, Binjiang District, Hangzhou, Zhejiang, China. <i>Hangzhou Huawei Enterprises</i> , No. 410 Jianghong Road, Building 1, Hangzhou, China. <i>Huawei Digital Technologies (Suzhou) Co., Ltd.</i> , No. 328 XINHU STREET, Building A3, Suzhou (Huawei R&D Center, Building A3, Creative Industrial Park, No. 328, Xinghu Street, Suzhou), Suzhou, Jiangsu, China.	For all items subject to the EAR, see §§ 736.2(b)(3)(vi)1, and 744.11 of the EAR, except for technology subject to the EAR that is designated as EAR99, or controlled on the Commerce Control List for anti-terrorism reasons only, when released to members of a “standards organization” (see § 772.1) for the purpose of contributing to the revision or development of a “standard” (see § 772.1).	Presumption of denial	84 FR 22963, 5/21/19. 84 FR 43495, 8/21/19. 85 FR 29853, 5/19/20. 85 FR 36720, 6/18/20. 85 FR 51603, 8/20/20. 86 FR [INSERT FR PAGE NUMBER 12/17/2021].

Country	Entity	License requirement	License review policy	Federal Register citation
	<p><i>Huawei Marine Networks Co., Ltd.</i>, a.k.a., the following four aliases: —Huawei Marine; —HMN Technologies; —Huahai Zhihui Technology Co., Ltd.; and —HMN Tech. Building R4, No. 2 City Avenue, Songshan Lake Science & Tech Industry Park, Dongguan, 523808, and No. 62, Second Ave., 5/F–6/F, TEDA, MSD–B2 Area, Tianjin Economic and Technological Development Zone, Tianjin, 300457, China.</p> <p><i>Huawei Mobile Technology Ltd.</i>, Huawei Base, Building 2, District B, Shenzhen, China.</p> <p><i>Huawei Tech. Investment Co.</i>, U1 Building, No. 1899 Xiyuan Avenue, West Gaoxin District, Chengdu City, 611731, China.</p> <p><i>Huawei Technology Co., Ltd. Chengdu Research Institute</i>, No. 1899, Xiyuan Ave., Hi-Tech Western District, Chengdu, Sichuan Province, 610041, China.</p> <p><i>Huawei Technology Co., Ltd. Hangzhou Research Institute</i>, No. 410, Jianghong Rd., Building 4, Changhe St., Binjiang District, Hangzhou, Zhejiang Province, 310007, China.</p> <p><i>Huawei Technologies Co., Ltd. Beijing Research Institute</i>, No. 3, Xinxu Rd., Huawei Building, ShangDi Information Industrial Base, Haidian District, Beijing, 100095, China; and No. 18, Muhe Rd., Building 1–4, Haidian District, Beijing, China.</p> <p><i>Huawei Technologies Co., Ltd. Material Characterization Lab</i>, Huawei Base, Bantian, Shenzhen 518129, China.</p> <p><i>Huawei Technologies Co., Ltd. Xi'an Research Institute</i>, National Development Bank Building (Zhicheng Building), No. 2, Gaoxin 1st Road, Xi'an High-tech Zone, Xi'an, China.</p> <p><i>Huawei Terminal (Shenzhen) Co., Ltd.</i>, Huawei Base, B1, Shenzhen, China.</p> <p><i>Nanchang Huawei Communication Technology</i>, No. 188 Huoju Street, F10–11, Nanchang, China.</p> <p><i>Ningbo Huawei Computer & Net Co., Ltd.</i>, No. 48 Daliang Street, Ningbo, China.</p> <p><i>Shanghai Huawei Technologies Co., Ltd.</i>, R&D center, No. 2222, Golden Bridge Road, Pu Dong District, Shanghai, 286305 Shanghai, China, China.</p> <p><i>Shenzhen Huawei Anjiexin Electricity Co., Ltd.</i>, a.k.a., the following one alias: —Shenzhen Huawei Agisson Electric Co., Ltd., Building 2, Area B, Putian Huawei Base, Longgang District, Shenzhen, China; and Huawei Base, Building 2, District B, Shenzhen, China.</p>			

Country	Entity	License requirement	License review policy	Federal Register citation
	<p><i>Shenzhen Huawei New Technology Co., Ltd.</i>, Huawei Production Center, Gangtou Village, Buji Town, Longgang District, Shenzhen, China.</p> <p><i>Shenzhen Huawei Technology Service</i>, Huawei Base, Building 2, District B, Shenzhen, China.</p> <p><i>Shenzhen Huawei Technologies Software</i>, Huawei Base, Building 2, District B, Shenzhen, China.</p> <p><i>Zhejiang Huawei Communications Technology Co., Ltd.</i>, No. 360 Jiangshu Road, Building 5, Hangzhou, Zhejiang, China.</p>			
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	Hyper Systems Union Limited, Unit A1 7/F Cheuk Nang Plaza, 250 Hennessy Road, Wan Chai, Hong Kong; and Rm. 905 Workingberg Commercial Bldg. 41–47 Marble Road Wan Chai, Hong Kong; and Flat D, 14/F., On Fook Ind. Bldg. 41–45 Kwai Fung Crescent, Kwai Chung, N.T., Hong Kong.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Inner Mongolia First Machinery Group Co., Ltd. a.k.a. the following three aliases: —China North Industries Group Corporation Limited (NORINCO) 617 Factory; —FIRMACO; and —Inner Mongolia One Machine. North Minzhu Road, Qingshan District, Baotou City, Inner Mongolia Autonomous Region, 014032 China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Integrated Scientific Microwave Technology, a.k.a., the following one alias: —ISM Tech. Rm. 1014 Favor Industrial Centre, 2–6 Kin Hong Street Kwai Chung Hong Kong (see alternate address under Malaysia).	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Jiangsu Hengtong Marine Cable Systems Co., Ltd., a.k.a., the following two aliases: —Jiangsu Hengtong Ocean Optical Network System Co., Ltd.; and —Smart Ocean System. No. 8, Tonga Road, Changshu Economic and Technological Development Zone, Suzhou City, Jiangsu Province.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Jiangsu Hengtong Optic-Electric Co., Ltd., a.k.a., the following three aliases: —Jiangsu Hengtong Photoelectric Co., Ltd.; —Hengtong Optoelectronics Co., Ltd.; and —HTGD. 88 Hengtong Avenue, Qidu Town, Wujiang District, Suzhou City, Jiangsu Province; and No. 2288, Zhongshan North Road, Wujiang District, Suzhou City, Jiangsu Province, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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Country	Entity	License requirement	License review policy	Federal Register citation
	ROV Solutions, Rm. 1014 Favour Industrial Centre, 2–6 Kin Hong Street Kwai Chung Hong Kong. (see alternate address under Georgia).	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Shaanxi Reactor Microelectronics Co., Ltd., Room 301, Block A, Hanyun Tower, Xi'an Software Park, No. 68, Keji 2nd Rd., High-Tech Zone, Xi'an, Shaanxi; and Room 103, Building 3, Zhongfu Commercial Advertising Park, Liuxian 2nd Road, Shenzhen City; and C37, Block C, Langda Plaza, Guzhen Town, Zhongshan City; and Room 604, Building 10, Baofen Yuanyuan No. 165, Baoqing Rd., Zhuangqiao St., Jiangbei District, Ningbo City, Zhejiang Province; and Room 105, Information Building, Three High Tech Road, Shaanxi, Xian, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Shanghai Aisinohip Electronics Technology Co., Ltd., a.k.a., the following two aliases: —Shanghai Aixinnuohangxin Electronic Technology Co., Ltd.; and —Aisino Chip. Building 702, Building 102, Phase 3, Science and Technology Oasis, No. 2570, Hechuan Rd., Minhang District, Shanghai.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Shanghai Aoshi Control Technology Co., Ltd., a.k.a. the following two aliases: —Shanghai Hengtong Optic-Electric Technology Co., Ltd.; and —Shanghai Hengtong Photoelectric Technology Co. Ltd. Building 1, No. 618 Chengliu Middle Road, Jiading District, Shanghai; and 1st Floor, Building 2, No. 555 Jiangchang West Road, Jing'an District, Shanghai, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Shenzhen Rion Technology, 4/F Block 1, Fuan Second Industrial Park, D Yang Tian, Da Yang Road, Ruyo, Shenzhen, China	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Thundsea Electric Limited, Rm. 1014 Favour Industrial Centre, 2–6 Kin Hong Street Kwai Chung Hong Kong; and Unit 1405B 14/F, The Belgian Bank Building, NOS. 721–725 Nathan Road Mongkok, Kowloon, Hong Kong	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Wavelet Electronics, Room 605, 6/F, Corporation Park, No. 11 on Lai Street, Shatin, New Territories, Hong Kong; and Building A2–3, Haufeng Industrial Park, Shiyan, Baoan District, Shenzhen, China RM 511, 5/F, Corporation Park, 11 ON LAI Street, Siu Lek Yuen, Shatin, N.T. Hong Kong.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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Country	Entity	License requirement	License review policy	Federal Register citation
	Zhongtian Technology Submarine Cable Co., Ltd., a.k.a., the following one alias: —ZTT Cable. No. 1, Xinkai South Road, Nantong Economic and Technological Development Zone, China.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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GEORGIA	Gensis Engineering, a.k.a., the following one alias: —Gensis Muhendislik Danismanlik. No. 2 Flat Loselianis Ave. Tbilisi, Georgia. (see alternate address under Turkey).	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	ROV Solutions, 12A Tahkenti Street, Tbilisi, Georgia. (see alternate address under China).	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	SAEROS Safety ERO Company, —No. 2 Flat Loselianis Ave. Tbilisi, Georgia.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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MALAYSIA	Integrated Scientific Microwave Technology, a.k.a., the following one alias: —ISM Tech. 1–11 1st floor, Jalan Padan Perdana 2, Dataran Pandan Prima, 55100, Kuala Lumpur, Malaysia. (see alternate address under China).	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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TURKEY	Gensis Engineering, a.k.a., the following one alias: —Gensis Muhendislik Danismanlik. Fevzi Cakmak Mah., Malazgirt Cad 58/5, Pendik, Istanbul, Turkey. (see alternate address under Georgia).	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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	Vangurd Tec Makina Sanyi Ithalat, Yesilkent MH. 2011 SK. Innovia 3 Etap 18/15 Esenyurt, Istanbul, Turkey.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER 12/17/2021].
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Matthew S. Borman,
Deputy Assistant Secretary for Export
Administration.

[FR Doc. 2021-27406 Filed 12-16-21; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2021-N-0857]

Medical Devices; General and Plastic Surgery Devices; Classification of the Manual Percutaneous Surgical Set Assembled in the Abdomen

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the manual percutaneous surgical set assembled in the abdomen into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the manual percutaneous surgical set assembled in the abdomen's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 17, 2021. The classification was applicable on April 30, 2012.

FOR FURTHER INFORMATION CONTACT: Cal Rabang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4633, Silver Spring, MD 20993-0002, 301-796-6412, Cal.Rabang@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the manual percutaneous surgical set assembled in the abdomen as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the

level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k) and part 807 (21 CFR part 807)).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo

classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application (PMA) to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on August 26, 2011, finding the Percutaneous Surgical Set with 5mm or 10mm Attachments not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On September 21, 2011, FDA received Ethicon Endo-Surgery, Inc.'s request for De Novo classification of the Percutaneous Surgical Set with 5mm or 10mm Attachments. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 30, 2012, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 878.4805.¹ We have named the

¹ FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to