

Country	Listed person and address	Federal Register citation and date of publication
*	Establishment Standard Lab FZE, a.k.a. Standard Lab FZE, Ras Al Khaimah Free Trade Zone Business Park, Ras Al Khaimah, UAE; and P.O. Box 17049, Ras Al Khaimah, UAE.	81 FR [INSERT Federal Register PAGE NUMBER, 6/21/16].
*	Marinatec, Office 2008, Grosvenor Commercial Tower, Sheikh Zayed Road, Dubai, UAE; and P.O. Box 42236, 17A Radisson Plaza, Deira, Dubai, UAE.	81 FR [INSERT Federal Register PAGE NUMBER, 6/21/16].
*	Middle East Oilfield Equipment, 723 Sama Tower, 6/F, near Fairmont Hotel, Sheikh Zayed Road, P.O. Box 4404, Dubai, UAE; and 217 Twin Towers, Baniyas Road, P.O. Box 4404, Deira, Dubai, UAE; and Flat 102, Mohammed Zainal Faraidooni Building, Salahuddin Road, Dubai, UAE.	81 FR [INSERT Federal Register PAGE NUMBER, 6/21/16].
*	Tek Work General Trading, 1902 Metropolis Business Tower, P.O. Box 12865, Business Bay, Dubai, UAE.	81 FR [INSERT Federal Register PAGE NUMBER, 6/21/16].

Dated: June 15, 2016.
Matthew S. Borman,
Deputy Assistant Secretary for Export Administration.
 [FR Doc. 2016-14514 Filed 6-20-16; 8:45 am]
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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 160415341-6341-01]

RIN 0694-AG94

Addition of Certain Persons and Removal of Certain Persons From 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 twenty-eight persons under thirty-one entries to the Entity List. The twenty-eight persons who are added to the Entity List have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States. These twenty-eight persons will be listed on the Entity List under the destinations of Afghanistan, Austria, China, Hong Kong, Iran, Israel, Panama, Taiwan, and the United Arab Emirates (U.A.E.).

This final rule also removes three entities from the Entity List under the destinations of Finland, Pakistan and Turkey as the result of requests for removal received by BIS pursuant to the

section of the EAR used for requesting removal or modification of an Entity List entity and the End-User Review Committee’s (ERC) review of the information provided in the removal requests.

DATES: This rule is effective June 21, 2016.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482-5991, Fax: (202) 482-3911, Email: *ERC@bis.doc.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Entity List (Supplement No. 4 to part 744) identifies entities and other persons reasonably believed to be involved, or to 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 imposes additional license requirements on, and limits the availability of most license exceptions for, exports, reexports, and transfers (in-country) to those listed. The “license review policy” for each listed entity or other person 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 **Federal Register** notice adding entities or other persons to the Entity List. BIS places entities and other persons on the Entity List pursuant to sections of part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

The 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 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 twenty-eight persons under thirty-one entries to the Entity List. These twenty-eight persons are being added on the basis of § 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 thirty-one entries added to the entity list consist of one entry in Afghanistan, one entry in Austria, two entries in China, six entries in Hong Kong, four entries in Iran, eight entries in Israel, one entry in Panama, four entries in Taiwan, and four entries in the U.A.E. There are thirty-one entries for the twenty-eight persons because three persons are listed in multiple locations, resulting in three additional entries.

The ERC reviewed § 744.11(b) (Criteria for revising the Entity List) in making the determination to add these twenty-eight persons under thirty-one entries to the Entity List. Under that paragraph, persons and those acting on behalf of such persons may be added to the Entity List if there is reasonable cause to believe, based on specific and articulable facts, that they have been

involved, are involved, or pose a significant risk of being or becoming involved in, activities that are contrary to the national security or foreign policy interests of the United States.

Paragraphs (b)(1) through (5) of § 744.11 include an illustrative list of activities that could be contrary to the national security or foreign policy interests of the United States.

Pursuant to § 744.11(b)(2) of the EAR, the ERC determined that twenty persons, located in the destinations of Afghanistan, Austria, China, Hong Kong, Iran, Taiwan, and the U.A.E., be added to the Entity List for actions contrary to the national security or foreign policy interests of the United States. The ERC determined that there is reasonable cause to believe, based on specific and articulable facts, that Mehrdad Rueen Foomanie, Mehrdad Moeinansari and related parties including Enrich Ever Technologies Co., Ltd.; Foang Tech Inc.; Global Merchant General Trading L.L.C.; Gulf Gate Sea Cargo L.L.C.; Gulf Gate Sea Cargo LLC; Gulf Gate Shipping Co. L.L.C.; Gulf Gate Spedition GmbH; Hivocal Technology Company, Ltd.; Infinity Wise Technology Limited; Kuang-Su Corporation; Morvarid Shargh Co. Ltd.; Morvarid Sanat Co. LTD; Ninehead Bird Semiconductor; Panda Semiconductor; Pinky Trading Co., Ltd.; Sazgan Ertebat Co. Ltd.; Well Smart (HK) Technology; and Wise Smart (HK) Electronics Limited, have been involved in actions contrary to the national security or foreign policy interests of the United States. Specifically, Foomanie and Moeinansari conducted nearly 600 transactions with 63 different U.S. companies in which they obtained or attempted to obtain U.S.-origin parts and components without notifying the U.S. companies that the parts would be shipped to Iran and without getting the required U.S. Government license to ship the parts and components to Iran. Foomanie and Moeinansari, with the assistance of companies located in Iran, arranged to have the items unlawfully shipped to Iran through companies located in Taiwan, Hong Kong and China. Additionally, Moeinansari attempted to transship and transshipped cargo originating in the United States using his company, Gulf Gate Sea Cargo LLC, located in Dubai, U.A.E.

In addition, pursuant to § 744.11(b) of the EAR, the ERC determined that eight persons, located in the destinations of Israel and Panama, be added to the Entity List for actions contrary to the national security or foreign policy interests of the United States. The ERC determined there is reasonable cause to believe, based on specific and

articulable facts, that Eliyahu Cohen and the following related persons: A. Leib Ltd.; AVS (Armored Vehicle Spares); M&P Trading Inc.; P.AD Ltd.; QPS Ltd.; RSP Ltd.; and Wheels Incorporated have been involved in activities that are contrary to the national security and foreign policy interests of the United States. Specifically, these persons procured and/or retransferred U.S.-origin items to Israel and Iran without having first obtained the required authorization or license from the U.S. Government.

Pursuant to § 744.11(b) of the EAR, the ERC determined that the conduct of these twenty-eight persons raises sufficient concern that prior review of exports, reexports or transfers (in-country) of items subject to the EAR involving these persons, and the possible imposition of license conditions or license denials on shipments to the persons, will enhance BIS's ability to prevent violations of the EAR. Therefore, these twenty-eight persons are being added to the Entity List under thirty-one entries.

For the twenty-eight persons under thirty-one entries added to the Entity List, BIS imposes a license requirement for all items subject to the EAR and a license review policy of presumption of denial. The license requirements apply to any transaction in which items are to be exported, reexported, or transferred (in-country) to any of the persons or in which such persons act as purchaser, intermediate consignee, ultimate consignee, or end-user. 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. The acronym "a.k.a." (also known as) is used in entries on the Entity List to help exporters, reexporters and transferors better identify listed persons on the Entity List.

This final rule adds the following twenty-eight persons under thirty-one entries to the Entity List:

Afghanistan

- (1) *Gulf Gate Sea Cargo LLC*,
Gulzaad Market Building, 4th Floor,
Room 2, Kabul, Afghanistan.

Austria

- (1) *Gulf Gate Spedition GmbH*,
A-1040 Argentinierstrasse 35/6,
Vienna, Austria.

China

- (1) *Foang Tech Inc.*, a.k.a., the following one alias:
—Ofogh Electronics Co.
52F, Shun Hing Square, Unit 1–8 Di
Wang Commercial Center,

Shenzhen, China (See alternate address under Hong Kong); *and*
(2) *Ninehead Bird Semiconductor*,
RM 15, Jufu Ge, Caifu Bld, Caitian
Road, Futian Qu, Shenzhen,
Guangdong, 518033, China.

Hong Kong

- (1) *Foang Tech Inc.*, a.k.a., the following one alias:
—Ofogh Electronics Co.
Flat/RM 1701-Ricky CTR, 36 Chowg
Yip Street, Kwun Tong, Hong Kong
(See alternate address under China);
- (2) *Infinity Wise Technology Limited*,
7/F One Kowloon, 1 Wang Yuen
Street, Kowloon Bay, Kowloon,
Hong Kong; *and* Room 1213 Chui
King House, Choi Hung Estate,
Kowloon, Hong Kong (See alternate
addresses under Taiwan);
- (3) *Panda Semiconductor*,
Room 2, Unit A 14/F Shun on
Commercial building, 112–114 Des
Voeux Road, Central, Hong Kong;
- (4) *Pinky Trading Co., Ltd.*,
338 Queen's Road, Central, Hong
Kong;
- (5) *Well Smart (HK) Technology*,
Room 604, Kalok Building, 720
Nathan Road, Kowloon, Hong Kong;
and
- (6) *Wise Smart (HK) Electronics Limited*,
Room 1213, Chui King House, Choi
Hung Estate, Kowloon, Hong Kong.

Iran

- (1) *Mehrdad Rueen Foomanie*, a.k.a., the following four aliases:
—Frank Foomanie;
—Mark Foomanie;
—Mark Averin; *and*
—Max Xian.
No. 35 Abaas Abaad Street, Daryosh
Street Andesheh 2 Street (Hamid
Qods), Iran—Tehran; *and*
Sohrivaridi Shomali Street,
Andesheh 2 Street, after Daryoush
Crossroad, No. 35, Floor 5, No. 8,
Tehran, Iran;
- (2) *Morvarid Sanat Co., Ltd.*,
Sohrivaridi Shomah Street, Andesheh
2 Street, after Daryosh Crossroad,
No. 35, Floor 5, No. 8, Tehran, Iran;
- (3) *Morvarid Shargh Co., Ltd.*,
Sohrivaridi Street No. 35, Tehran, Iran;
and
- (4) *Sazgan Ertebat Co., Ltd.*, a.k.a., the following one alias:
—Sazgan Ertebat Poya Co. Ltd.
No. 40-Hoveizeh St. Sohrivaridi St.,
Tehran, Iran; *and* P.O. Box 16315–
194 Zip: 1559934314.

Israel

- (1) *A. Leib Ltd.*,
HA'Assif 19, Binyamina, Israel;
- (2) *AVS (Armored Vehicle Spares)*,
a.k.a., the following one alias:

- Armored Vehicle Service.
42 Hamesilla Street, Binyamina,
Israel;
- (3) *Eliyahu Cohen*, a.k.a., the following
six aliases:
—Arie Cohen;
—Eli Cohen;
—Eliyahu Ari Cohen;
—Eliyahu Arie Cohen;
—Eric Cohen; *and*
—Ari Kohan.
Binyamina, Israel.
- (4) *M&P Trading Inc.*,
P.O. Box 161, Caesarea, Israel
3088903;
- (5) *P.AD Ltd.*,
42 Hamesilla Street, Binyamina,
Israel;
- (6) *QPS Ltd.*, a.k.a., the following two
aliases:
—Quality Parts and Spares; *and*
—Quality Parts and Services.
5 Ner Halayla Street, Caesarea, Israel;
and 42 Hamesilla Street, Railway
Industrial Area, Binyamina, Israel;
- (7) *RSP Ltd.*, a.k.a., the following one
alias:
—Rebuilt Spare Parts.
HA'Assif 19, Binyamina, Israel 30550;
and
- (8) *Wheels Incorporated*,
HA'Assif 43, Binyamina, Israel 30551
(See alternate address under
Panama).

Panama

- (1) *Wheels Incorporated*,
P.O. Box 6—2875, El Dorado, Panama
(See alternate address under Israel).

Taiwan

- (1) *Enrich Ever Technologies Co., Ltd.*,
a.k.a., the following one alias:
—Enrich Ever Technologies Co.
9F No. 38 Ming-Fu 13th Street,
Taoyuan, Taiwan; *and*
8F, No. 431, Da-You Road, Taoyuan,
Taiwan;
- (2) *Hivocal Technology Company, Ltd.*;
10F, No. 736, Jhonggheng Road,
Jhonghe City, Taipei County 235,
Taiwan;
- (3) *Infinity Wise Technology Limited*,
Flat/RMA 6/F, Man Wing Building
503–507 Nathan Road Yaumate 1,
Taiwan; *and* 8F, No. 431, Da-You
Road Taoyuan, Taiwan (See
alternate addresses under Hong
Kong); *and*
- (4) *Kuang-Su Corporation*,
8F, No. 431, Da-You Road, Taoyuan,
Taiwan.

United Arab Emirates

- (1) *Global Merchant General Trading
LLC*,
P.O. Box 39960, Dubai, U.A.E.;
- (2) *Gulf Gate Sea Cargo LLC*,
No. 508, Bldg P–114, Almaktoom

- Road, Deirah, Dubai, United Arab
Emirates; *and* P.O. Box 39948,
Dubai, U.A.E.;
- (3) *Gulf Gate Shipping Co. LLC*,
No. 508, Bldg P–114, Almaktoom
Road, Deirah, Dubai, United Arab
Emirates; *and* P.O. Box 39948,
Dubai, U.A.E.; *and*
- (4) *Mehrdad Moeinansari*, a.k.a., the
following one alias:
—Mehrdad Ansari.
No 7101, Index Tower DIFC, Dubai,
U.A.E.; *and* No 508, Sheikh
Maryam Bldg., Deirah, Dubai,
U.A.E. 39948.

Removals From the Entity List

This rule implements the decisions of
the ERC to remove the following three
entries from the Entity List based on
removal requests received by the BIS:
Nurminen Oy, located in Finland;
Rayyan Air Pvt Ltd., located in Pakistan;
and AAG Makina, located in Turkey.

The ERC's decisions to remove
Nurminen Oy, Rayyan Air Pvt Ltd *and*
AAG Makina from the Entity List were
based on information received by the
BIS pursuant to § 744.16 of the Export
Administration Regulation *and* further
review conducted by the ERC.

In accordance with § 744.16(c), the
Deputy Assistant Secretary for Export
Administration has sent written
notification informing these three
persons of the ERC's decisions to
remove them from the Entity List.

This final rule implements the
decisions to remove the following three
entities located in Finland, Pakistan *and*
Turkey from the Entity List:

Finland

- (1) *Nurminen Oy*,
231B Vanha Porvoontie, Vantaa,
Finland 01380.

*Note that while Nurminen Oy is being
removed, Olkebor Oy is being retained
on the Entity List in this final rule.*

Pakistan

- (1) *Rayyan Air Pvt Ltd.*,
House No 614 Street No 58 I–8/2
Islamabad, Pakistan; *and* Office No
456, K Street No 57 I–8/3
Islamabad, Pakistan.

Turkey

- (1) *AAG Makina*,
Mah. Idris Kosku Caddesi Kutu,
Sokak No:1 Pierreloti/Eyup,
Istanbul, Turkey.

The removal of the three persons
referenced above, which was approved
by the ERC, eliminates the existing
license requirements in Supplement No.
4 to part 744 for exports, reexports *and*
transfers (in-country) to these entities.

However, the removal of these three
persons from the Entity List does not
relieve persons of other obligations
under part 744 of the EAR or under
other parts of the EAR. Neither the
removal of an entity from the Entity List
nor the removal of Entity List-based
license requirements relieves persons of
their obligations under General
Prohibition 5 in § 736.2(b)(5) of the EAR
which provides that, “you may not,
without a license, knowingly export or
reexport any item subject to the EAR to
an end-user or end-use that is
prohibited by part 744 of the EAR.”
Additionally, these removals do not
relieve persons of their obligation to
apply for export, reexport or in-country
transfer licenses required by other
provisions of the EAR. BIS strongly
urges the use of Supplement No. 3 to
part 732 of the EAR, “BIS's ‘Know Your
Customer’ Guidance *and* Red Flags,”
when persons are involved in
transactions that are subject to the EAR.

Savings Clause

Shipments of items removed from
eligibility for a License Exception or
export or reexport without a license
(NLR) as a result of this regulatory
action that were en route aboard a
carrier to a port of export or reexport, on
June 21, 2016, pursuant to actual orders
for export or reexport to a foreign
destination, may proceed to that
destination under the previous
eligibility for a License Exception or
export or reexport without a license
(NLR).

Export Administration Act

Although the Export Administration
Act expired on August 20, 2001, the
President, through Executive Order
13222 of August 17, 2001, 3 CFR, 2001
Comp., p. 783 (2002), as amended by
Executive Order 13637 of March 8,
2013, 78 FR 16129 (March 13, 2013) *and*
as extended by the Notice of August 7,
2015, 80 FR 48233 (August 11, 2015),
has continued the Export
Administration Regulations in effect
under the International Emergency
Economic Powers Act. BIS continues to
carry out the provisions of the Export
Administration Act, as appropriate *and*
to the extent permitted by law, pursuant
to Executive Order 13222, as amended
by Executive Order 13637.

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 nor 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 carries a burden estimate of 43.8 minutes for a manual or electronic submission. Total burden hours associated with the PRA and OMB control number 0694-0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to Jasmeet.K.Seehra@omb.eop.gov, or by fax to (202) 395-7285.

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

4. For the twenty-eight persons under thirty-one entries added to the Entity List in this final rule, the provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment and a delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States. (See 5 U.S.C. 553(a)(1).) BIS implements this rule to protect U.S. national security or foreign policy interests by preventing items from being exported, reexported, or transferred (in country) to the persons being added to the Entity List. If this rule were delayed to allow for notice and comment and a delay in effective date, the entities being added to the Entity List by this action would continue to be able to receive items without a license and to conduct activities contrary to the national security or foreign policy interests of the United States. In addition, publishing a

proposed rule would give these parties notice of the U.S. Government's intention to place them on the Entity List and would create an incentive for these persons to either accelerate receiving items subject to the EAR to conduct activities that are contrary to the national security or foreign policy interests of the United States, and/or to take steps to set up additional aliases, change addresses, and other measures to try to limit the impact of the listing on the Entity List once a final rule was published. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. 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.

5. For the three entries removed from the Entity List in this final rule, pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), BIS finds good cause to waive requirements that this rule be subject to notice and the opportunity for public comment because it would be contrary to the public interest.

In determining whether to grant removal requests from the Entity List, a committee of U.S. Government agencies (the End-User Review Committee (ERC)) evaluates information about and commitments made by listed persons requesting removal from the Entity List, the nature and terms of which are set forth in 15 CFR part 744, Supplement No. 5, as noted in 15 CFR 744.16(b). The information, commitments, and criteria for this extensive review were all established through the notice of proposed rulemaking and public comment process (72 FR 31005 (June 5, 2007) (proposed rule), and 73 FR 49311 (August 21, 2008) (final rule)). These three removals have been made within the established regulatory framework of the Entity List. If the rule were to be delayed to allow for public comment, U.S. exporters may face unnecessary economic losses as they turn away potential sales to the other entities removed by this rule because the customer remained listed persons on the Entity List even after the ERC approved the removals pursuant to the rule published at 73 FR 49311 on August 21, 2008. By publishing without prior notice and comment, BIS allows the applicants to receive U.S. exports immediately since the applicants

already have received approval by the ERC pursuant to 15 CFR part 744, Supplement No. 5, as noted in 15 CFR 744.16(b).

The removals from the Entity List granted by the ERC involve interagency deliberation and result from review of public and non-public sources, including sensitive law enforcement information and classified information, and the measurement of such information against the Entity List removal criteria. This information is extensively reviewed according to the criteria for evaluating removal requests from the Entity List, as set out in 15 CFR part 744, Supplement No. 5 and 15 CFR 744.16(b). For reasons of national security, BIS is not at liberty to provide to the public detailed information on which the ERC relied to make the decisions to remove these three entities. In addition, the information included in the removal request is information exchanged between the applicant and the ERC, which by law (section 12(c) of the Export Administration Act), BIS is restricted from sharing with the public. Moreover, removal requests from the Entity List contain confidential business information, which is necessary for the extensive review conducted by the U.S. Government in assessing such removal requests.

Section 553(d) of the APA generally provides that rules may not take effect earlier than thirty (30) days after they are published in the **Federal Register**. BIS finds good cause to waive the 30-day delay in effectiveness under 5 U.S.C. 553(d)(1) because this rule is a substantive rule which relieves a restriction. This rule's removal of three persons under three entries from the Entity List removes a requirement (the Entity-List-based license requirement and limitation on use of license exceptions) on these three persons being removed from the Entity List. The rule does not impose a requirement on any other person for these three removals from the Entity List.

No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required under the APA or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. As a result, no final 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 through 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. 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. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; 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 August 7, 2015, 80 FR 48233 (August 11, 2015);

Notice of September 18, 2015, 80 FR 57281 (September 22, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015); Notice of January 20, 2016, 81 FR 3937 (January 22, 2016).

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

- a. By adding under Afghanistan, in alphabetical order, one Afghan entity;
- b. By adding in alphabetical order, an entry for Austria and one Austrian entity;
- c. By adding under China, People’s Republic of, in alphabetical order, two Chinese entities;
- d. By removing under Finland, the Finnish entity, “Olkebor Oy/Nurminen Oy” and adding in its place the Finnish entity, “Olkebor Oy”;
- e. By adding under Hong Kong, in alphabetical order, six Hong Kong entities;

- f. By adding under Iran, in alphabetical order, four Iranian entities;
- g. By adding under Israel, in alphabetical order, eight Israeli entities;
- h. By removing under Pakistan, one Pakistani entity, “Rayyan Air Pvt Ltd.”;
- i. By adding under Panama, in alphabetical order, one Panamanian entity;
- j. By adding under Taiwan, in alphabetical order, four Taiwanese entities;
- k. By removing under Turkey, one Turkish entity, “AAG Makina”; and
- l. By adding under United Arab Emirates, in alphabetical order, four Emirati entities.

The additions and revisions read as follows:

SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST

Country	Entity	License requirement	License review policy	Federal Register citation
AFGHANISTAN	* Gulf Gate Sea Cargo LLC, Gulzaad Market Building, 4th Floor, Room 2, Kabul, Afghanistan.	* For all items subject to the EAR. (See § 744.11 of the EAR).	* Presumption of denial	* 81 FR [INSERT FR PAGE NUMBER] 6/21/16.
AUSTRIA	* Gulf Gate Spedition GmbH, A–1040 Argentinierstrasse 35/6, Vienna, Austria.	* For all items subject to the EAR. (See § 744.11 of the EAR).	* Presumption of denial	* 81 FR [INSERT FR PAGE NUMBER] 6/21/16.
CHINA, PEOPLE’S REPUBLIC OF	* Foang Tech Inc., a.k.a., the following one alias: —Ofogh Electronics Co. 52F, Shun Hing Square, Unit 1–8 Di Wang Commercial Center, Shenzhen, China (See alternate address under Hong Kong).	* For all items subject to the EAR. (See § 744.11 of the EAR).	* Presumption of denial	* 81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	* Ninehead Bird Semiconductor, RM 15, Jufu Ge, Caifu Bld, Caitian Road, Futian Qu, Shenzhen, Guangdong, 518033, China.	* For all items subject to the EAR. (See § 744.11 of the EAR).	* Presumption of denial	* 81 FR [INSERT FR PAGE NUMBER] 6/21/16.
FINLAND	* Olkebor Oy, 231B Vanha Porvoontie, Vantaa, Finland 01380.	* For all items subject to the EAR. (See § 744.11 of the EAR).	* Presumption of denial	* 77 FR 61256, 10/9/12. 78 FR 3319, 1/16/13. 81 FR [INSERT FR PAGE NUMBER] 6/21/16.
HONG KONG	* Foang Tech Inc., a.k.a., the following one alias: —Ofogh Electronics Co. Flat/RM 1701–Ricky CTR, 36 Chowg Yip Street, Kwun Tong, Hong Kong (See alternate address under China).	* For all items subject to the EAR. (See § 744.11 of the EAR).	* Presumption of denial	* 81 FR [INSERT FR PAGE NUMBER] 6/21/16.

SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

Country	Entity	License requirement	License review policy	Federal Register citation
	Infinity Wise Technology Limited, 7/F One Kowloon, 1 Wang Yuen Street, Kowloon Bay, Kowloon, Hong Kong; <i>and</i> Room 1213 Chui King House, Choi Hung Estate, Kowloon, Hong Kong (See alternate addresses under Taiwan).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
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	Panda Semiconductor, Room 2, Unit A 14/F Shun on Commercial building, 112–114 Des Voeux Road, Central, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	Pinky Trading Co., Ltd., 338 Queen's Road, Central, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
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	Well Smart (HK) Technology, Room 604, Kalok Building, 720 Nathan Road, Kowloon, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	Wise Smart (HK) Electronics Limited, Room 1213, Chui King House, Choi Hung Estate, Kowloon, Hong Kong.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
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IRAN	*	*	*	*
	Mehrdad Ruen Foomanie, a.k.a., the following four aliases: —Frank Foomanie; —Mark Foomanie; —Mark Averin; <i>and</i> —Max Xian.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	No. 35 Abaas Abaad Street, Daryosh Street Andesheh 2 Street (Hamid Qods), Iran—Tehran; <i>and</i> Sohrivardi Shomali Street, Andesheh 2 Street, after Daryoush Crossroad, No. 35, Floor 5, No. 8, Tehran, Iran.			
	*	*	*	*
	Morvarid Sanat Co. Ltd., Sohrivardi Shomah Street, Andesheh 2 Street, after Daryosh Crossroad, No. 35 Floor 5, No. 8, Tehran, Iran.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	Morvarid Shargh Co. Ltd., Sohrivardi Street No. 35, Tehran, Iran.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
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	Sazgan Ertebat Co. Ltd., a.k.a., the following one alias: —Sazgan Ertebat Poya Co. Ltd. No. 40-Hoveizeh St. Sohrevardi St., Tehran, Iran; <i>and</i> P.O. Box 16315–194 Zip: 1559934314.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	*	*	*	*
ISRAEL	*	*	*	*
	A. Leib Ltd.; HA'Assif 19, Binyamina, Israel.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	AVS (Armored Vehicle Spares), a.k.a., the following one alias: —Armored Vehicle Service. 42 Hamesilla Street, Binyamina, Israel.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
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SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

Country	Entity	License requirement	License review policy	Federal Register citation
	Eliyahu Cohen, a.k.a., the following six aliases: —Arie Cohen; —Eli Cohen; —Eliyahu Ari Cohen; —Eliyahu Arie Cohen; —Eric Cohen; <i>and</i> —Ari Kohan. Binyamina, Israel.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	M&P Trading Inc., P.O. Box 161, Caesarea, Israel 3088903.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	P.AD Ltd., 42 Hamesilla Street, Binyamina, Israel.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	QPS Ltd., a.k.a., the following two aliases: —Quality Parts and Spares; <i>and</i> —Quality Parts and Services. 5 Ner Halayla Street, Caesarea, Israel; <i>and</i> 42 Hamesilla Street, Railway Industrial Area, Binyamina, Israel.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	RSP Ltd., a.k.a., the following one alias: —Rebuilt Spare Parts. HA'Assif 19, Binyamina, Israel 30550.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	Wheels Incorporated, HA'Assif 43, Binyamina, Israel 30551 (See alternate address under Panama).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
PANAMA	Wheels Incorporated, P.O. Box 6—2875, El Dorado, Panama (See alternate address under Israel).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
TAIWAN	Enrich Ever Technologies Co., Ltd., a.k.a., the following one alias: —Enrich Ever Technologies Co., 9F No. 38 Ming-Fu 13th Street, Taoyuan, Taiwan; <i>and</i> 8F, No. 431, Da-You Road, Taoyuan, Taiwan.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	Hivocal Technology Company, Ltd., 10F, No. 736, Jhongjheng Road, Jhonghe City, Taipei County 235, Taiwan.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	Infinity Wise Technology Limited, Flat/RMA 6/F, Man Wing Building 503–507 Nathan Road Yaumate 1, Taiwan; <i>and</i> 8F, No. 431, Da-You Road Taoyuan, Taiwan (See alternate addresses under Hong Kong).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	Kuang-Su Corporation, 8F, No. 431, Da-You Road, Taoyuan, Taiwan.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
UNITED ARAB EMIRATES	Global Merchant General Trading LLC, P.O. Box 39960, Dubai, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.

SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

Country	Entity	License requirement	License review policy	Federal Register citation
	Gulf Gate Sea Cargo LLC, No. 508, Bldg P-114, Almaktoom Road, Deirah, Dubai, United Arab Emirates; and P.O. Box 39948, Dubai, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	Gulf Gate Shipping Co. LLC, No. 508, Bldg P-114, Almaktoom Road, Deirah, Dubai, United Arab Emirates; and P.O. Box 39948, Dubai, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	Mehrdad Moeinansari, a.k.a., the following one alias: —Mehrdad Ansari, No 7101, Index Tower DIFC, Dubai, U.A.E.; and No 508, Sheikha Maryam Bldg., Deirah, Dubai, U.A.E. 39948.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
*	*	*	*	*

Dated: June 9, 2016.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2016-14515 Filed 6-20-16; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA-2016-N-1318]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Gynecologic Laparoscopic Power Morcellation Containment System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the gynecologic laparoscopic power morcellation containment system into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the gynecologic laparoscopic power morcellation containment system's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective June 21, 2016. The classification was applicable on April 7, 2016.

FOR FURTHER INFORMATION CONTACT: Veronica Price, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G116, Silver Spring, MD 20993-0002, 301-796-6538, veronica.price@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendment devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and,

within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On June 19, 2015, Advanced Surgical Concepts submitted a request for classification of the PneumoLiner device under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set