§ 746.6 Crimea region of Ukraine.

(a) *License requirements*—(1) *General prohibition.* As authorized by Section 6 of the Export Administration Act of 1979, a license is required to export or reexport any item subject to the EAR, other than food and medicine designated as EAR99, to the Crimea region of Ukraine. The 'Crimea region of Ukraine' includes the land territory in that region as well as any maritime area over which sovereignty, sovereign rights, or jurisdiction is claimed based on purported sovereignty over that land territory. This license requirement includes transfers within the Crimea region.

(b) *License review policy.* Applications will be reviewed with a presumption of denial, except for items authorized under OFAC Ukraine-Related General License No. 4 which will be reviewed on a case-by-case basis.

(c) *License exceptions.* You may export, reexport or transfer (in-country) without a license if your transaction meets all the applicable terms and conditions of any of the license exception paragraphs specified in this paragraph (c). To determine scope and eligibility requirements, you will need to refer to the sections or specific paragraphs of part 740 (License Exceptions). Read each license exception carefully, as the provisions available for countries subject to sanctions are generally narrow.

(1) TMP for items for use by the news media as set forth in § 740.9(a)(9) of the EAR.

(2) GOV for items for personal or official use by personnel and agencies of the U.S. Government, the International Atomic Energy Agency (IAEA), or the European Atomic Energy Community (Euratom) as set forth in § 740.11(a) and (b)(2) of the EAR.

(3) GFT for gift parcels and humanitarian donations as set forth in § 740.12.

(4) TSU for operation technology and software for lawfully exported commodities as set forth in § 740.13(a) and sales technology as set forth in § 740.13 (b) of the EAR.

(5) BAG for exports of items by individuals leaving the United States as personal baggage as set forth in § 740.14(a) through (d) of the EAR.

(6) AVS for civil aircraft and vessels as set forth in § 740.15(a)(4) and (d) of the EAR.

PART 772—[AMENDED]

■ 7. The authority citation for 15 CFR part 738 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014).

■ 8. Section 772.1 is amended by revising the definition for the term ''Food'' to read as follows:

§ 772.1 Definitions of terms as used in the Export Administration Regulations (EAR).

* * * * *

Food. Specific to exports and reexports to North Korea, Syria and Crimea region of Ukraine, food means items that are consumed by and provide nutrition to humans and animals, and seeds, with the exception of castor bean seeds, that germinate into items that will be consumed by and provide nutrition to humans and animals. (Food does not include alcoholic beverages.)

* * * * *

Dated: January 23, 2015.

Eric L. Hirschhorn,

Under Secretary of Commerce for Industry and Security.

[FR Doc. 2015–01638 Filed 1–28–15; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 141104925–4925–01]

RIN 0694–AG35

Revisions to the Unverified List (UVL)

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) by adding fourteen (14) persons, removing one person, and updating the addresses of other persons listed on the Unverified List (the ''Unverified List'' or UVL). The 14 persons are being added to the UVL on the basis that BIS could not verify their *bona fides* because an end-use check could not be completed satisfactorily for reasons outside the U.S. Government's control. One person is removed from the UVL based on BIS's ability to verify that person's *bona fides* through the successful completion of an end-use check. Also, new addresses are added for two listed persons on the UVL.

DATES: *Effective date:* This rule is effective: January 29, 2015.

FOR FURTHER INFORMATION CONTACT: Kevin Kurland, Director, Office of Enforcement Analysis, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–4255 or by email at *UVLRequest@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Supplement No. 6 to Part 744 (''the UVL'') contains the names and addresses of foreign persons who are or have been parties to a transaction, as that term is described in § 748.5 of the EAR, involving the export, reexport, or transfer (in-country) of items subject to the EAR, and whose *bona fides* BIS has been unable to verify through an end-use check. BIS may add persons to the UVL when BIS or federal officials acting on BIS's behalf have been unable to verify a foreign person's *bona fides* (*i.e.,* legitimacy and reliability relating to the end use and end user of items subject to the EAR) because an end-use check, such as a pre-license check (PLC) or a post-shipment verification (PSV), cannot be completed satisfactorily for such purposes for reasons outside the U.S. Government's control.

End-use checks cannot be completed for a number of reasons, including reasons unrelated to the cooperation of the foreign party subject to the end-use check. For example, BIS sometimes initiates end-use checks and cannot find a foreign party at the address indicated on export documents, and cannot locate the party by telephone or email. Additionally, BIS sometimes is unable to conduct end-use checks when host government agencies do not respond to requests to conduct end-use checks, are prevented from scheduling such checks by a party to the transaction other than the foreign party that is the proposed subject of the end-use check, or refuse to schedule them in a timely manner. Under these circumstances, although BIS has an interest in informing the public of its inability to verify the foreign party's *bona fides,* there may not be sufficient information to add the foreign persons at issue to the Entity List under § 744.11 of the EAR (Criteria for revising the Entity List). In such circumstances, BIS may add the foreign persons to the UVL.

Furthermore, BIS sometimes conducts end-use checks but cannot verify the *bona fides* of a foreign party. For example, BIS may be unable to verify *bona fides* if during the conduct of an end-use check a recipient of items subject to the EAR is unable to produce those items for visual inspection or provide sufficient documentation or other evidence to confirm the disposition of those items. The inability of foreign persons subject to end-use checks to demonstrate their *bona fides* raises concerns about the suitability of such persons as participants in future

exports, reexports, or transfers (in-country) and indicates a risk that items subject to the EAR may be diverted to prohibited end uses and/or end users. However, BIS may not have sufficient information to establish that such persons are involved in activities described in part 744 of the EAR, preventing the placement of the persons on the Entity List. In such circumstances, the foreign persons may be added to the Unverified List.

As provided in § 740.2(a)(17) of the EAR, the use of license exceptions for exports, reexports, and transfers (in-country) involving a party or parties to the transaction who are listed on the UVL is suspended. Additionally, under § 744.15(b) of the EAR, there is a requirement for exporters, reexporters, and transferors to obtain (and keep a record of) a UVL statement from a party or parties to the transaction who are listed on the UVL before proceeding with exports, reexports, and transfers (in-country) to such persons, when the exports, reexports and transfers (in-country) are not subject to a license requirement.

Requests for removal of a UVL entry must be made in accordance with § 744.15(d) of the EAR. Decisions regarding the removal or modification of UVL listings will be made by the Deputy Assistant Secretary for Export Enforcement, based on a demonstration by the listed person of its *bona fides.*

Changes to the EAR

Supplement No. 6 to Part 744 (''the Unverified List'' or ''UVL'')

Among other things, this rule adds fourteen (14) persons to the UVL by amending Supplement No. 6 to Part 744 of the EAR to include their names and addresses. BIS adds these persons in accordance with the criteria for revising the UVL set forth in § 744.15(c) of the EAR. The new entries consist of eleven persons located in Hong Kong, two persons located in Pakistan, and one person located in the United Arab Emirates. Each listing is grouped within the UVL by country, and accompanied by the party's name(s), available alias(es), and address(es), as well as the **Federal Register** citation and the date the person was added to the UVL. The UVL is included in the Consolidated Screening List, available at *www.export.gov.*

This rule also adds new addresses for two current UVL persons, Narpel Technologies, Ltd. and Powersun Electronics, both located in Hong Kong. BIS has determined that these persons are receiving U.S. exports at addresses other than those originally included in their UVL entries.

Lastly, this rule removes from the UVL one company, Dynasense Photonics Co., Ltd. in Hong Kong, based on BIS's ability to confirm its *bona fides* through the successful completion of an end-use check. The removal of the above referenced person from the UVL eliminates the restrictions against the use of license exceptions and the requirements specific to exports, reexports and transfers (in-country) not otherwise requiring a license to the person, as described in § 744.15 of the EAR. However, the removal of this person from the UVL does not relieve persons proposing to export, reexport or transfer (in-country) items subject to the EAR to the removed person of other obligations under part 744 of the EAR or under other parts of the EAR. Neither the removal of a person from the UVL nor the removal of UVL-based restrictions and requirements relieves a person of the obligation to obtain a license if the person knows that an export or reexport of any item subject to the EAR is destined to an end user or end use set forth in part 744 other than § 744.15 of the EAR. Additionally, this removal does 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 (1) removed from license exception eligibility or that are now subject to requirements in § 744.15 of the EAR as a result of this regulatory action, (2) eligible for export, reexport, or transfer (in-country) without a license before this regulatory action, and (3) on dock for loading, on lighter, laden aboard an exporting carrier, or en route aboard a carrier to a port of export, on January 29, 2015, pursuant to actual orders, may proceed to that UVL listed person under the previous license exception eligibility or without a license so long as the items have been exported from the United States, reexported or transferred (in-country) before March 2, 2015. Any such items not actually exported, reexported or transferred (in-country) before midnight, on March 2, 2015, are subject to the requirements in § 744.15 of the EAR in accordance with this regulation.

Export Administration Act

Since August 21, 2001, the Export Administration Act of 1979, as amended, has been in lapse. However, 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, 2014, 79 FR 46959 (August 11, 2014) has continued the EAR in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*). 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 not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866.

2. 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 to this rule, which is adding 14 persons, removing one person, and updating the addresses of two other persons listed on the UVL, because this regulation involves military or foreign affairs. BIS implements this rule to protect U.S. national security or foreign policy interests by requiring a license for items being exported, reexported, or transferred (in country) involving a party or parties to the transaction who are listed on the UVL. If this rule were delayed to allow for notice and comment and a delay in effective date, the entities being added to the UVL by this action and those entities operating at previously unlisted addresses would continue to be able to receive items without additional oversight by BIS 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 UVL, 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 once a final rule was published.

The Department finds there is good cause under 5 U.S.C. 553(b)(3)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment to the provision of this rule removing one person from the UVL because doing so is contrary to the public interest and unnecessary. The removal is being made following the completion of a successful end-use check. 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 because the customer remained a listed person on the UVL even after BIS was able to verify that entity's *bona fides* through an end-use check. By publishing without prior notice and comment, BIS allows the entity to receive U.S. exports as quickly as possible following their cooperation in a successful end-use check. By quickly removing entities from the UVL following the successful completion of an end-use check, BIS encourages other entities to cooperate in end-use checks requested by BIS. 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.

3. Notwithstanding any other provision of law, no person is required to respond to, nor is 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 the following control numbers: 0694–0088, 0694–0122, 0694–0134, and 0694–0137.

This rule slightly increases public burden in a collection of information approved by OMB under control number 0694–0088, which authorizes, among other things, export license applications. The removal of license exceptions for listed persons on the Unverified List will result in increased license applications being submitted to BIS by exporters. Total burden hours associated with the Paperwork Reduction Act and OMB control number 0694–0088 are expected to increase minimally, as the suspension of license exceptions will only affect transactions involving persons listed on the Unverified List and not all export transactions. Because license exceptions are restricted from use, this rule decreases public burden in a collection of information approved by OMB under control number 0694–0137 minimally, as this will only affect specific individual listed persons. The increased burden under 0694–0088 is reciprocal to the decrease of burden under 0694–0137, and results in no change of burden to the public. This rule also increases public burden in a collection of information under OMB control number 0694–0122, as a result of the exchange of UVL statements between private parties, and under OMB control number 0694–0134, as a result of appeals from persons listed on the UVL for removal of their listing. The total increase in burden hours associated with both of these collections is expected to be minimal, as they involve a limited number of persons listed on the UVL.

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

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. app. 2401 *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 January 21, 2014, 79 FR 3721 (January 22, 2014); Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of September 17, 2014, 79 FR 56475 (September 19, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014).

■ 2. Supplement No. 6 to Part 744 is amended by:

■ a. Removing the entry for ''Dynasense Photonics Co., Limited'';

■ b. Revising the entry for ''Narpel Technology Co., Limited'';

■ c. Revising the entry for ''Powersun Electronics'';

■ d. Adding an entry for ''Pakistan''; and

■ e. Adding 11 entries, in alphabetical order, under ''Hong Kong''; and

■ f. Adding an entry, in alphabetical order, under the ''United Arab Emirates''.

The revisions and additions read as follows:

Supplement No. 6 to Part 744—Unverified List

* * * * *

Country	Listed person and address	**Federal Register** citation and date of publication
*	* * * * *	*
HONG KONG	AST Technology Group (HK) Ltd., Flat 6, 20/F, Mega Trade Centre, 1–9 Mei Wan Street, Tsuen Wan, Hong Kong; *and* Unit 2209, 22/F, Wu Chung House, 213, Queen's Road East, Wan Chai, Hong Kong.	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
*	* * * * *	*
	Daystar Electric (HK) Ltd., Flat D, 19/F, Waylee Industrial Centre, 30–38 Tsuen King Circuit, Tsuen Wan, New Territories, Hong Kong; *and* 9/F Kam Chung Commercial Building, 19–21 Hennessy Road, Wanchai, Hong Kong.	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.

Country	Listed person and address	**Federal Register** citation and date of publication
	Ditis Hong Kong Ltd., Room 227–228, 2/F, Metre Centre II, 21 Lam Hing Street, Kowloon Bay, Kowloon, Hong Kong; *and* Rooms 1318–1320, Hollywood Plaza, 610 Nathan Road, Mong Kok, Kowloon, Hong Kong; *and* Room 205, 2/F, Sunley Centre, 9 Wing Yin Street, Kwai Chung, New Territories, Hong Kong.	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
*	* * * * * *	*
	E-Chips Technology, Unit 4, 7/F, Bright Way Tower, No. 33 Mong Kok Road, Mong Kok, Kowloon, Hong Kong.	80 FR [INSERT FR PAGE] January 29, 2015.
	GS Technology Ltd., a.k.a. GS Technology Group Ltd., Flat 6, 20/F, Mega Trade Centre, 1–9 Mei Wan Street, Tsuen Wan, New Territories, Hong Kong; *and* Unit D, 16/F, Cheuk Nang Plaza, 250 Hennessy Road, Wanchai, Hong Kong.	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
*	* * * * * *	*
	Hong Kong U.Star Electronics Technology Co., Ltd., Room 28, 8/F, Shing Yip Industrial Building, 19–21 Shing Yip Street, Kwun Tong, Kowloon, Hong Kong; *and* Unit 5, 27/F, Richmond Commercial Building, 109 Argyle Street, Mong Kok, Kowloon, Hong Kong.	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
	Hongbo Industrial Technology, Unit 3, 9/F, Shing Yip Industrial Building, 19–21 Shing Yip Street, Kwun Tong, Kowloon, Hong Kong; *and* Unit 04, 7/F, Bright Way Tower, No. 33, Mong Kok Road, Kowloon, Hong Kong.	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
*	* * * * * *	*
	Ling Ao Electronic Technology Co. Ltd., a.k.a. Voyage Technology (HK) Co. Ltd., Room 17, 7/F, Metro Centre Phase 1, No. 32 Lamhing St., Kowloon Bay, Hong Kong; *and* 15B, 15/F, Cheuk Nang Plaza, 250 Hennessy Road, Hong Kong.	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
*	* * * * * *	*
	Microlink Communication Ltd., Room 806, 8/F, Kenbo Commercial Building, No. 335–339 Queen's Road West, Hong Kong.	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
	Milectronic Communication Ltd., Room 2912, Tower 2, Times Square, 1 Matheson Street, Causeway Bay, Hong Kong.	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
*	* * * * * *	*
	Narpel Technology Co., Limited, Unit A, 6/F, Yip Fat Factory Building, Phase 1, No 77 Hoi Yuen Road, Kwun Tong, Kowloon, Hong Kong; *and* Room 4C, 8/F, Sunbeam Centre, 27 Shing Yip Street, Kwun Tong, Kowloon, Hong Kong; *and* Room 1905, Nam Wo Hong Building, 148 Wing Lok Street, Sheung Wan, Hong Kong.	79 FR 34217, 06/16/14, 80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
*	* * * * * *	*
	Powersun Electronics, Flat/Rm 502D, Hang Pont Commercial Building, 31 Tonkin Street, Cheung Sha Wan, Kowloon, Hong Kong; *and* G/F and G/M, Winner Godown Building, 1–9 Sha Tsui Road, Tsuen Wan, New Territories, Hong Kong.	79 FR 34217, 06/16/14, 80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
*	* * * * * *	*
	Suke Logistics Ltd., Flat 6, 20/F, Mega Trade Centre, 1–9 Mei Wan Street, Tsuen Wan, New Territories, Hong Kong.	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
*	* * * * * *	*
PAKISTAN	Fauji Fertilizer Company Ltd., 156 The Mall Rawalpindi Cantt, Pakistan	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
	T.M.A. International, a.k.a. TMA International, a.k.a. Tahir Asad Industries Pvt. Ltd., a.k.a. T.A. Industries Pvt. Ltd., 45–B, Ahmed Block, New Garden Town, Lahore, Pakistan; *and* 417 Gulshan Block, Iqbal Town, Lahore, Pakistan.	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
*	* * * * * *	*
UNITED ARAB EMIRATES	Rich Star General Trading LLC, #203 The Atrium Centre, Khalid bin Waleed Road, Bur Dubai, Dubai, UAE; *and* P.O. Box 181977, Dubai, UAE.	80 FR [INSERT FR PAGE NUMBER] January 29, 2015.
*	* * * * * *	*

Dated: January 23, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–01639 Filed 1–28–15; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2013–N–0234]

Effective Date of Requirement for Premarket Approval for Automated External Defibrillator Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a final order to require the filing of premarket approval applications (PMA) for automated external defibrillator (AED) systems, which consist of an AED and those AED accessories necessary for the AED to detect and interpret an electrocardiogram and deliver an electrical shock (*e.g.,* pad electrodes, batteries, adapters, and hardware keys for pediatric use).

DATES: This order is effective on January 29, 2015.

FOR FURTHER INFORMATION CONTACT: Linda Ricci, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1314, Silver Spring, MD 20993, 301–796–6325, *linda.ricci@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act (21 U.S.C. 360c(d)), devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as ''preamendments devices''), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as ''postamendments devices'') are automatically classified by section 513(f) of the FD&C Act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is 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 (21 U.S.C. 360c(i)), 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).

A preamendments device that has been classified into class III and devices found substantially equivalent by means of premarket notification (510(k)) procedures to such a preamendments device or to a device within that type (both the preamendments and substantially equivalent devices are referred to as preamendments class III devices) may be marketed without submission of a premarket approval application (PMA) until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval or until the device is subsequently reclassified into class I or class II. Section 515(b)(1) of the FD&C Act (21 U.S.C. 360e(b)(1)) directs FDA to issue an order requiring premarket approval for a preamendments class III device.

Although, under the FD&C Act, the manufacturer of a class III preamendments device may respond to the call for PMAs by filing a PMA or a notice of completion of a product development protocol (PDP), in practice, the option of filing a notice of completion of a PDP has not been used. For simplicity, although corresponding requirements for PDPs remain available to manufacturers in response to a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)), this document will refer only to the requirement for the filing and receiving approval of a PMA.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended section 513(e) of the FD&C Act (21 U.S.C. 360c(e)), changing the mechanism for reclassifying a device from rulemaking to an administrative order. Section 608(b) of FDASIA amended section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) changing the mechanism for requiring premarket approval for a preamendments class III device from rulemaking to an administrative order.

Section 515(b)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order requiring premarket approval for a preamendments class III device, the following must occur: (1) Publication of a proposed order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments from all affected stakeholders, including patients, payers, and providers.

Section 515(b)(3) of the FD&C Act provides that FDA shall, after the close of the comment period on the proposed order, consideration of any comments received, and a meeting of a device classification panel described in section 513(b) of the FD&C Act, issue a final order to require premarket approval or publish a document terminating the proceeding together with the reasons for such termination.

A preamendments class III device may be commercially distributed without a PMA until 90 days after FDA issues a final order (a final rule issued under section 515(b) of the FD&C Act prior to the enactment of FDASIA is considered to be a final order for purposes of section 501(f) of the FD&C Act (21 U.S.C. 351(f))) requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the FD&C Act, whichever is later. For AED systems, the later of these two time periods is the 90-day period. Therefore, section 501(f)(2)(B) of the FD&C Act (21 U.S.C. 351(f)(2)(B)) requires that a PMA