

TABLE 13 TO PARAGRAPH (F)(1) TO § 431.97—MINIMUM EFFICIENCY STANDARDS FOR VARIABLE REFRIGERANT FLOW MULTI-SPLIT AIR CONDITIONERS AND HEAT PUMPS—Continued

Equipment type	Cooling capacity	Heating type <sup>1</sup>	Efficiency level	Compliance date: equipment manufactured on and after . . .
	≥65,000 Btu/h and <135,000 Btu/h .....	All .....	12.0 EER, 4.2 COP .....	October 29, 2003.
	≥135,000 Btu/h and <760,000 Btu/h .....	Without Heat Recovery .....	10.0 EER, 3.9 COP .....	October 29, 2013.
		With Heat Recovery .....	9.8 EER, 3.9 COP .....	October 29, 2013.

<sup>1</sup> VRF multi-split heat pumps (air-cooled) with heat recovery fall under the category of “All Other Types of Heating” unless they also have electric resistance heating, in which case it falls under the category for “No Heating or Electric Resistance Heating.”

(2) Each variable refrigerant flow air conditioner or heat pump (except air-cooled systems with cooling capacity less than 65,000 Btu/h) manufactured on or after January 1, 2024, must meet the applicable minimum energy efficiency standard level(s) set forth in table 14 of this section.

TABLE 14 TO PARAGRAPH (F)(2) TO § 431.97—UPDATED MINIMUM EFFICIENCY STANDARDS FOR VARIABLE REFRIGERANT FLOW MULTI-SPLIT AIR CONDITIONERS AND HEAT PUMPS

Equipment type	Size category	Heating type	Minimum efficiency
VRF Multi-Split Air Conditioners (Air-Cooled) .....	≥65,000 and <135,000 Btu/h .....	All .....	15.5 IEER.
	≥135,000 and <240,000 Btu/h .....	All .....	14.9 IEER.
	≥240,000 Btu/h and <760,000 Btu/h .....	All .....	13.9 IEER.
VRF Multi-Split Heat Pumps (Air-Cooled) .....	≥65,000 and <135,000 Btu/h .....	Heat Pump without Heat Recovery .....	14.6 IEER, 3.3 COP.
		Heat Pump with Heat Recovery .....	14.4 IEER, 3.3 COP.
	≥135,000 and <240,000 Btu/h .....	Heat Pump without Heat Recovery .....	13.9 IEER, 3.2 COP.
		Heat Pump with Heat Recovery .....	13.7 IEER, 3.2 COP.
	≥240,000 Btu/h and <760,000 Btu/h .....	Heat Pump without Heat Recovery .....	12.7 IEER, 3.2 COP.
		Heat Pump with Heat Recovery .....	12.5 IEER, 3.2 COP.
VRF Multi-Split Heat Pumps (Water-Source) .....	<65,000 Btu/h .....	Heat Pump without Heat Recovery .....	16.0 IEER, 4.3 COP.
		Heat Pump with Heat Recovery .....	15.8 IEER, 4.3 COP.
		Heat Pump without Heat Recovery .....	16.0 IEER, 4.3 COP.
	≥65,000 and <135,000 Btu/h .....	Heat Pump with Heat Recovery .....	15.8 IEER, 4.3 COP.
		Heat Pump without Heat Recovery .....	14.0 IEER, 4.0 COP.
		Heat Pump with Heat Recovery .....	13.8 IEER, 4.0 COP.
	≥135,000 and <240,000 Btu/h .....	Heat Pump without Heat Recovery .....	12.0 IEER, 3.9 COP.
		Heat Pump with Heat Recovery .....	12.0 IEER, 3.9 COP.
		Heat Pump with Heat Recovery .....	11.8 IEER, 3.9 COP.

\* \* \* \* \*  
 [FR Doc. 2023-06178 Filed 3-29-23; 8:45 a.m.]  
 BILLING CODE 6450-01-P

**DEPARTMENT OF COMMERCE**  
**Bureau of Industry and Security**

**15 CFR Part 744**

[Docket No. 230324-0084]

RIN 0694-AJ20

**Additions to the Entity List; Amendment To Confirm Basis for Adding Certain Entities to the Entity List Includes Foreign Policy Interest of Protection of Human Rights Worldwide**

**AGENCY:** Bureau of Industry and Security, Department of Commerce.  
**ACTION:** Final rule.

**SUMMARY:** In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by adding eleven entities to the Entity List under the destinations of Burma, the People’s Republic of China (China), Nicaragua, and Russia. These eleven entities have been determined by

the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States. In this rule, BIS also amends the EAR to explicitly confirm that the foreign policy interest of protecting human rights worldwide is a basis for adding entities to the Entity List.

**DATES:** This rule is effective on March 28, 2023.

**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](mailto:ERC@bis.doc.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

The Entity List (supplement no. 4 to part 744 of the EAR (15 CFR parts 730 through 774)) 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, pursuant

to § 744.11(b). The EAR impose additional license requirements on, and limit the availability of, most license exceptions for exports, reexports, and transfers (in-country) when a listed entity is a party to the transaction. 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 that added the entity to the Entity List. The Bureau of Industry and Security (BIS) places entities on the Entity List pursuant to parts 744 (Control Policy: End-User and End-Use Based) and 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.

## Entity List Decisions

### A. Additions to the Entity List

The ERC determined to add two entities, Aviatech and Aviazapchast, under the destination of Russia, and three entities, Miya Win, Myanmar New Era Trading Company, and Suntac Group, under the destination of Burma, to the Entity List for engaging in activities contrary to U.S. foreign policy interests. These additions are being made because Aviatech, Aviazapchast, Miya Win, Myanmar New Era Trading Company, and Suntac Group sell, procure, and service military equipment that enables Burma's military regime to carry out human rights abuses, as well as brutal aerial attacks that have killed and injured civilians. These activities are contrary to the foreign policy interests of the United States under § 744.11(b) of the EAR. For these five entities, BIS imposes a license requirement for all items subject to the EAR and will review license applications under a presumption of denial.

The ERC determined to add the Nicaraguan National Police (NNP) to the Entity List under the destination of Nicaragua for engaging in activities contrary to U.S. foreign policy interests. This addition is being made because the NNP is responsible for or complicit in, or has directly or indirectly engaged in, serious human rights abuses in Nicaragua. These activities are contrary to the foreign policy interests of the United States under § 744.11(b) of the EAR. For this entity, BIS imposes a license requirement for all items subject to the EAR and will review license applications under a presumption of denial.

The ERC determined to add the following five entities: Luopu Haishi Dingxin Electronic Technology Co., Ltd., Moyu Haishi Electronic Technology Co., Ltd., Pishan Haishi Yong'an Electronic Technology Co., Ltd., Urumqi Haishi Xin'an Electronic Technology Co., Ltd., and Yutian Haishi Meitian Electronic Technology Co., Ltd., to the Entity List under the destination of China, for engaging in activities contrary to U.S. foreign policy interests. These additions are being made because Luopu Haishi Dingxin Electronic Technology Co., Ltd., Moyu Haishi Electronic Technology Co., Ltd., Pishan Haishi Yong'an Electronic Technology Co., Ltd., Urumqi Haishi Xin'an Electronic Technology Co., Ltd., and Yutian Haishi Meitian Electronic Technology Co., Ltd. have been implicated in human rights violations and abuses in the implementation of China's campaign of repression, mass

arbitrary detention and high-technology surveillance against the Uyghur people and members of other Muslim minority groups in the Xinjiang Uyghur Autonomous Region (XUAR). These activities are contrary to the foreign policy interests of the United States under § 744.11(b) of the EAR. For these five entities, BIS imposes a license requirement for all items subject to the EAR and will review license applications under a presumption of denial.

For the reasons described above, this final rule adds the following eleven entities to the Entity List and includes, where appropriate, aliases:

#### Burma

- Miya Win International Ltd.,
- Myanmar New Era Trading Company Ltd., *and*
- Suntac Group.

#### China

- Luopu Haishi Dingxin Electronic Technology Co., Ltd.,
- Moyu Haishi Electronic Technology Co., Ltd.,
- Pishan Haishi Yong'an Electronic Technology Co., Ltd.,
- Urumqi Haishi Xin'an Electronic Technology Co., Ltd., *and*
- Yutian Haishi Meitian Electronic Technology Co., Ltd.,

#### Nicaragua

- Nicaraguan National Police (NNP).

#### Russia

- Aviatech Supply Ltd., *and*
- Aviazapchast PLC.

### B. Amendment to § 744.11—License Requirements That Apply to Entities Acting or at Significant Risk of Acting Contrary to the National Security or Foreign Policy Interests of the United States: Explicit Inclusion of Protection of Human Rights To Further U.S. Foreign Policy Interests

As part of BIS's ongoing review and update of the EAR to further the foreign policy interest of protecting human rights, consistent with the Export Control Reform Act of 2018 (ECRA), in this rule BIS amends the "Criteria for revising the Entity List" paragraph (b) introductory text and the "is informed" provisions of paragraph (c)(3) (Additional prohibition on persons informed by BIS) of § 744.11 to explicitly confirm a longstanding position that the protection of human rights throughout the world is a foreign policy interest considered in assessing whether the activities of an entity—and those acting on behalf of such entity are contrary to the national security or

foreign policy of the United States. This amendment is consistent with the foreign policy objectives set forth at 50 U.S.C. 4811(2)(D), which include the protection of human rights and promotion of democracy.

BIS is amending this provision to confirm this foreign policy interest and its potential application to the Entity List, similar to the current illustrative list of examples of activities that could lead to an entity's addition to the Entity List, as set forth in § 744.11(b)(1)–(5) of the EAR. This amendment is consistent with the recent decision by the United States Court of Appeals for the District of Columbia Circuit in *Changji Esquel Textile Co. Ltd. v. Raimondo*, 40 F.4th 716 (2022), which affirmed BIS's authority to add parties to the Entity List for human rights-related reasons. In that case, the Court found that "[a]dding human-rights violators to the Entity List falls comfortably within" the scope of 50 U.S.C. 4813(a)(16), which authorizes the Secretary of Commerce to "undertake any other action as is necessary to carry out this subchapter that is not otherwise prohibited by law," and that it did not "discern any clear and mandatory prohibition on adding entities to the [Entity] List for human-rights abuses, particular given the breadth of section 4813(a)(16) and the deference we owe to the Executive Branch in matters of foreign affairs." *Id.* at 723, 725.

Further, and as noted by the Court in the *Esquel* decision (*Id.* at 720), years before the enactment of ECRA, BIS made explicit reference in its Entity List rules to the agency's longstanding authority to take action under the Entity List to address human rights concerns. For example, the background sections of two Entity List rules published in November 2012 and April 2014, respectively, each cite a range of "grounds for inclusion," among them "activities contrary to U.S. national security or foreign policy interests, including terrorism and export control violations involving abuse of human rights" (77 FR 71,097 (Nov. 29, 2012)); 79 FR 21,394 (Apr. 16, 2014)). These rules relied upon authority set forth in the Export Administration Act of 1979, as amended, (50 U.S.C. 4601–4623 (Supp. III 2015)), specifically, Section 6 (Foreign Policy Controls). This provision's Congressional supporters intended that foreign policy controls apply to human rights concerns, including "changing the human rights policy of another country." H.R. Rep. No. 96–200, at 7 (1979) (Comm. Rep.).

Savings Clause

For the changes being made in this final rule, 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 March 28, 2023, 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) before April 27, 2023. Any such items not actually exported, reexported, or transferred (in-country) before midnight, on April 27, 2023, require a license in accordance with this final rule.

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. 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 an information collection approved by OMB under control number 0694–0088, Simplified Network Application Processing System. BIS does not anticipate a change to the burden hours associated with this collection as a result of this rule. Information regarding the collection, including all supporting materials, can be accessed at <https://www.reginfo.gov/public/do/PRAMain>.

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

4. Pursuant to section 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 through 774) is amended as follows:

**PART 744—CONTROL POLICY: END-USER AND END-USE BASED**

■ 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 19, 2022, 87 FR 57569 (September 21, 2022); Notice of November 8, 2022, 87 FR 68015 (November 10, 2022).

■ 2. Section 744.11 is amended by revising the last sentence of paragraph (b) introductory text and the first sentence of paragraph (c)(3) to read as follows:

**§ 744.11 License Requirements that Apply to Entities Acting or at Significant Risk of Acting Contrary to The National Security or Foreign Policy Interests of the United States.**

\* \* \* \* \*

(b) \* \* \* Paragraphs (b)(1) through (5) of this section provide an illustrative list of activities that could be or represent a significant risk of being contrary to the national security or foreign policy interests of the United States, including the foreign policy interest of the protection of human rights throughout the world.

\* \* \* \* \*

(c) \* \* \*

(3) The export, reexport, or transfer (in-country) of specified items to a certain party because there is reasonable cause to believe, based on specific and articulable facts, that the entity has been involved, is involved, or poses 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, including the foreign policy interest of the protection of human rights throughout the world, and those acting on behalf of such entity. \* \* \*

■ 3. Supplement no. 4 to part 744 is amended by:

■ a. Under BURMA, adding entries in alphabetical order for “Miya Win International Ltd.,” “Myanmar New Era Trading Company Ltd.,” and “Suntac Group”;

■ b. Under CHINA, PEOPLE’S REPUBLIC OF, adding entries in alphabetical order for “Luopu Haishi Dingxin Electronic Technology Co., Ltd.,” “Moyu Haishi Electronic Technology Co., Ltd.,” “Pishan Haishi Yong’an Electronic Technology Co., Ltd.,” “Urumqi Haishi Xin’an Electronic Technology Co., Ltd.,” and “Yutian Haishi Meitian Electronic Technology Co., Ltd.”;

■ c. Adding in alphabetical order the destination of NICARAGUA under the Country Column, and the entry “Nicaraguan National Police (NNP)”;

■ d. Under RUSSIA, adding entries in alphabetical order for “Aviatech Supply Ltd.” and “Aviazapchast PLC”.

The additions read as follows:

**Supplement No. 4 to Part 744—Entity List**

\* \* \* \* \*

Country	Entity	License requirement	License review policy	Federal Register citation
*	*	*	*	*
BURMA	*	*	*	*

Country	Entity	License requirement	License review policy	Federal Register citation
	Miya Win International Ltd., 3rd street, Thit Sarhousing, No.3/401, (8) Ward, South Okkalapatownship, Yangon Region, Burma, 11091; <i>and</i> Kokkineresidence Street, No.12/B, Shwe Taungkyar (2) Ward, Bahan Township, Yangon Region, Burma, 11201.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial .....	88 FR [INSERT FR PAGE NUMBER ] 3/30/2023.
	*	*	*	*
	Myanmar New Era Trading Company Ltd., Bo Myint Swe Street, No. (B/193), Aung Chan Thar (2) Ward, Thanlyin Township, Yangon Region, Burma, 01-655200.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial .....	88 FR [INSERT FR PAGE NUMBER] 3/30/2023.
	*	*	*	*
	Suntac Group, a.k.a., the following one alias: -Suntac International Trading Co.; <i>and</i> -Suntac Group of Companies. 151 (B) Thiri Mingalar Lane, Mayangon Township, Yangon, Burma.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial .....	88 FR [INSERT FR PAGE NUMBER] 3/30/2023.
	*	*	*	*
CHINA, PEOPLE'S REPUBLIC OF	*	*	*	*
	Luopu Haishi Dingxin Electronic Technology Co., Ltd., a.k.a., the following two aliases: -Luo Pu District HaiShi Ding Xin Electronic Technology Co., Ltd.; <i>and</i> -Luopu County Haishi Dingxin Electronic Technology Co., Ltd. No.8, South Side, National Highway 315, Luopu County Petroleum Company Hotan Prefecture, Xinjiang, 848201 China.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial .....	88 FR [INSERT FR PAGE NUMBER ] 3/30/2023.
	*	*	*	*
	Moyu Haishi Electronic Technology Co., Ltd., No. 7, Yinhe North Road, Moyu County Hotan Prefecture, Xinjiang, 848100 China.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial .....	88 FR [INSERT FR PAGE NUMBER ] 3/30/2023.
	*	*	*	*
	Pishan Haishi Yong'an Electronic Technology Co., Ltd., a.k.a., the following two aliases: -PiShan Haishi YongAn Electronic Technology Co., Ltd.; <i>and</i> -Pishan Haishi Yongan Electronic Technology Co., Ltd. No. 28, Guma North Road, Pishan County, Hotan Prefecture, Xinjiang, 845150 China.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial .....	88 FR [INSERT FR PAGE NUMBER ] 3/30/2023.
	*	*	*	*
	Urumqi Haishi Xin'an Electronic Technology Co., Ltd., Room 5010-5021, Block A, Yingke Plaza, No. 217 Gaoxin Street, Xinshi District, High-tech Industrial Development Zone Wulumuqi, Xinjiang, 830011 China.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial .....	88 FR [INSERT FR PAGE NUMBER ] 3/30/2023.
	*	*	*	*
	Yutian Haishi Meitian Electronic Technology Co., Ltd., No. 9, Tuanjie Road, Yutian County Hotan Prefecture, Xinjiang, 848499 China.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial .....	88 FR [INSERT FR PAGE NUMBER ] 3/30/2023.
	*	*	*	*
NICARAGUA	Nicaraguan National Police (NNP), 4PJP+GFP, Managua 11132, Nicaragua.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial .....	88 FR [INSERT FR PAGE NUMBER ] 3/30/2023.

Country	Entity	License requirement	License review policy	Federal Register citation
*	*	*	*	*
RUSSIA	Aviatech Supply Ltd., a.k.a., the following two aliases: -Aviatech; and -Aviatechexport Ltd. 630123, Airport St. Build.1A, 3rd Floor, Novosibirsk, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial .....	88 FR [INSERT FR PAGE NUMBER] 3/30/2023
	Aviazapchast PLC, 48, Ivana Franko Street, Moscow, 121351, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial .....	88 FR [INSERT FR PAGE NUMBER] 3/30/2023.
*	*	*	*	*

\* \* \* \* \*

**Thea D. Rozman Kendler,**  
Assistant Secretary for Export Administration.

[FR Doc. 2023-06663 Filed 3-28-23; 4:15 pm]  
BILLING CODE 3510-33-P

**SECURITIES AND EXCHANGE COMMISSION**

**17 CFR Part 240**

**General Rules and Regulations, Securities Exchange Act of 1934**

*CFR Correction*

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 17 of the Code of Federal Regulations, Part 240, revised as of April 1, 2022, in section 240.13e-100, reinstate the paragraphs at the end of the section following “Item 16. Exhibits” to read as follows:

**§ 240.13e-100 Schedule 13E-3, Transaction statement under section 13(e) of the Securities Exchange Act of 1934 and Rule 13e-3 (§ 240.13e-3) thereunder.**

\* \* \* \* \*

*Signature.* After due inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Name and title)

\_\_\_\_\_  
(Date)

*Instruction to Signature:* The statement must be signed by the filing person or that person’s authorized representative. If the statement is signed

on behalf of a person by an authorized representative (other than an executive officer of a corporation or general partner of a partnership), evidence of the representative’s authority to sign on behalf of the person must be filed with the statement. The name and any title of each person who signs the statement must be typed or printed beneath the signature. See § 240.12b-11 with respect to signature requirements.

[FR Doc. 2023-06701 Filed 3-29-23; 8:45 am]  
BILLING CODE 0099-10-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 888**

[Docket No. FDA-2021-N-0310]

RIN 0910-AI32

**Medical Devices; Orthopedic Devices; Classification of Spinal Spheres for Use in Intervertebral Fusion Procedures**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is issuing a final rule to classify spinal spheres for use in intervertebral fusion procedures (an unclassified, preamendments device) into class III for which FDA is separately requiring the filing of a premarket approval application (PMA). FDA has determined that general controls and special controls together are insufficient to provide reasonable assurance of safety and effectiveness for this device.

**DATES:** This rule is effective May 1, 2023.

**ADDRESSES:** For access to the docket to read background documents or

comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this final rule, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Constance Soves, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1656, Silver Spring, MD 20993-0002, 301-796-6951, [Constance.Soves@fda.hhs.gov](mailto:Constance.Soves@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

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**I. Executive Summary**

*A. Purpose of the Final Rule*

FDA is classifying spinal spheres for use in intervertebral fusion procedures (spinal spheres), which are unclassified, preamendments devices, into class III. A