Country	Entity	License requirement	License review policy	**Federal Register** citation
	St. Petersburg Shipbuilding Institution Krylov 45, a.k.a., the following one alias: —Krylov State Research Center. 44 Moskovskoe Highway, St. Petersburg, Russia, 196158.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR.)	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	87 FR [INSERT FR PAGE NUMBER] 6/6/2022.
	* *	*	* *	*
	Strategic Control Posts Corporation, a.k.a., the following two aliases: —Central Design Bureau of Heavy Machine Building SPU TsKB TM; *and* —JSC Corporation SPU–CCB TM. 12A Vozvodnaya St., Moscow, 111024, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR.)	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	87 FR [INSERT FR PAGE NUMBER] 6/6/2022.
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	Systems of Biological Synthesis LLC., a.k.a., the following three aliases: —Sistemy Biologicheskogo Sinteza; —OOO SBS; *and* —SBS LLC. Akademika Koroleva Street, Building 13/1, Office 35–39, Moscow, 129515, Russia.	For all items subject to the EAR (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER] 6/6/2022.
	TsKB MT Rubin, a.k.a., the following two aliases: —Tsentralnoe Konstruktorskoe Byuro Morskoi Tekhniki Rubin; *and* —The Rubin Central Design Bureau for Marine Engineering. 90 Marata Street, Saint Petersburg, 191119, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR.)	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	87 FR [INSERT FR PAGE NUMBER] 6/6/2022.
	* *	*	* *	*
	V.A. Trapeznikov Institute of Control Sciences of Russian Academy of Sciences, a.k.a., the following two aliases: —ICS RAS; *and* —IPU RAS. 65 Profsoyuznaya Street, Business Center Vozdvizhenka Center Voentorg, Moscow, 117997, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR.)	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	87 FR [INSERT FR PAGE NUMBER] 6/6/2022.
	Vladimir Design Bureau for Radio Communications OJSC, a.k.a., the following one alias: —VKBR. 28 Baturina St., Vladimir, Vladimirskaya oblast, 600017, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR.)	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	87 FR [INSERT FR PAGE NUMBER] 6/6/2022.
	Voentelecom JSC, 15A/1 Bolshaya Olenya St., Moscow, 107014, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR.)	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	87 FR [INSERT FR PAGE NUMBER] 6/6/2022.
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Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2022–12144 Filed 6–2–22; 4:15 pm]

BILLING CODE 3510–JT–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2022–N–0790]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Non-Implanted Electrical Stimulation Device for Management of Premature Ejaculation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the non-implanted electrical stimulation device for management of premature ejaculation into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the non-implanted electrical stimulation device for management of premature ejaculation's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective June 6, 2022. The classification was applicable on November 23, 2021.

FOR FURTHER INFORMATION CONTACT: Feba Abraham, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2647, Silver Spring, MD 20993–0002, 307–796–5772, *Feba.Abraham@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the non-implanted electrical stimulation device for management of premature ejaculation as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

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

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

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

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

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

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 30, 2021, FDA received Virility Medical's request for De Novo classification of the vPatch. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

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

Therefore, on November 23, 2021, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 876.5026.[1] We have named the generic type of device non-implanted electrical stimulation device for management of premature ejaculation, and it is identified as a device intended to be used in patients with premature ejaculation by delivery of electrical stimulation to the perineal muscles and nerves.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—NON-IMPLANTED ELECTRICAL STIMULATION DEVICE FOR MANAGEMENT OF PREMATURE EJACULATION RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Use error leading to patient pain, discomfort, or injury.	Labeling.
Electrical, mechanical or thermal fault, system malfunction, or other device failure resulting in lack of treatment or patient discomfort/injury (*e.g.,* electrical shock, burn, tissue damage, or interference from other medical devices or electrical equipment).	Non-clinical performance testing; Electrical safety testing; Electromagnetic compatibility testing; Software validation, verification, and hazard analysis; Shelf-life testing; and Labeling.
Adverse tissue reaction.	Biocompatibility evaluation, and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY–UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.5026 to subpart F to read as follows:

§ 876.5026 Non-implanted electrical stimulation device for management of premature ejaculation.

(a) *Identification.* A non-implanted electrical stimulation device for management of premature ejaculation is intended to be used in patients with premature ejaculation by delivery of electrical stimulation to the perineal muscles and nerves.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device must be demonstrated to be biocompatible.

(2) Performance testing must demonstrate the electromagnetic compatibility, electrical safety, and thermal safety of the device.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Mechanical performance;

(ii) Electrical stimulation parameters; and

(iii) Battery performance.

(4) Performance testing must support shelf life by demonstrating continued device functionality over the identified shelf life.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Labeling must include:

(i) Specific instructions regarding safe placement and correct use of the device;

(ii) Warning(s) against use by patients with active implanted medical devices; and

(iii) A shelf life.

Dated: May 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12082 Filed 6–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–568]

Schedules of Controlled Substances: Placement of Methoxetamine (MXE) in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the Controlled Substances Act to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle, methoxetamine.

DATES: Effective July 6, 2022.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a specific schedule, the Secretary of the Department Health and Human Services (HHS),[1] after consultation with the Attorney General, shall determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[2] In the event that the Secretary of HHS did not consult with the Attorney General, and

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the Controlled Substances Act, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

[2] 21 U.S.C. 811(d)(3).