At the time of classification, general laparoscopic power morcellation containment systems are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

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 the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' 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 regulations, 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 878

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 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

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

■ 2. Add § 878.4825 to subpart E to read as follows:

§ 878.4825 General laparoscopic power morcellation containment system.

(a) *Identification.* A general laparoscopic power morcellation containment system is a prescription device consisting of an instrument port and tissue containment method that creates a working space allowing for direct visualization during a power morcellation procedure following a laparoscopic procedure for the excision of benign tissue that is not suspected to contain malignancy.

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

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Performance testing must demonstrate the sterility of patient-contacting components of the device.

(3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life.

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

(i) Demonstration of the device impermeability to tissue, cells, and fluids;

(ii) Demonstration that the device allows for the insertion/withdrawal of laparoscopic instruments while maintaining pneumoperitoneum;

(iii) Demonstration that the containment system provides adequate space to perform morcellation and adequate visualization of the laparoscopic instruments and tissue specimen relative to the external viscera;

(iv) Demonstration that compatible laparoscopic instruments and morcellators do not compromise the integrity of the containment system; and

(v) Demonstration that users can adequately deploy the device, morcellate a specimen without compromising the integrity of the device, and remove the device without spillage of contents.

(5) Training must be developed and validated to ensure users can follow the instructions for use.

(6) Labeling must include:

(i) A contraindication for use in gynecological procedures;

(ii) A contraindication against use of tissue that is known or suspected to contain malignancy;

(iii) The following boxed warning: ''Warning: Information regarding the potential risks of a procedure with this device should be shared with patients. The use of laparoscopic power morcellators may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk;''

(iv) A statement limiting use of device to physicians who have completed the training program; and

(v) A shelf life.

Dated: November 17, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25585 Filed 11–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 0

[Directive No. 2021–001]

Designation of Authority

AGENCY: Office of the Assistant Attorney General, Criminal Division, Department of Justice.

ACTION: Final rule.

SUMMARY: The Attorney General has authorized the Assistant Attorney General for the Criminal Division to perform the functions of the ''Designated Authority'' under executive agreements between the United States and other countries on access to data by foreign governments and to delegate that authority to certain officials in the Office of International Affairs (''OIA''). Consistent with that authorization, the Assistant Attorney General for the Criminal Division delegates authority to perform the functions of the Designated Authority pursuant to such agreements to the Deputy Assistant Attorneys General, Criminal Division, and the Director, Deputy Directors and the Associate Director supervising the implementation of such agreements in OIA.

DATES: Effective November 23, 2021.

FOR FURTHER INFORMATION CONTACT: Vaughn Ary, Director, Office of International Affairs, Criminal Division, U.S. Department of Justice, Washington, DC 20005; Telephone (202) 514–0000.

SUPPLEMENTARY INFORMATION: Congress authorized the United States to enter into executive agreements with foreign governments under which the parties afford each other reciprocal rights of

access to data covered by such agreements in response to qualifying, lawful orders. *See* Clarifying Lawful Overseas Use of Data Act, Public Law 115–141, Div. V, Section 105(a) (March 23, 2018), 18 U.S.C. 2523 (''CLOUD Act''). The first such executive agreement was concluded between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland. *See* Agreement between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland on Access to Electronic Data for the Purpose of Countering Serious Crime (October 3, 2019), available at *https://www.justice.gov/dag/cloudact* (the ''U.S.—U.K. Agreement''). The U.S.—U.K. Agreement provides that a ''Designated Authority'' for each country shall perform certain, specified functions necessary to implement the agreement. As applied to the United States, ''Designated Authority'' is defined under the agreement as ''the governmental entity designated . . . by the Attorney General.'' *Id.* at Article 1.8. To address the requirements of this executive agreement, the Attorney General has designated the Criminal Division as the ''Designated Authority'' in a **Federal Register** notice published on October 23, 2020. The Attorney General has authorized the Assistant Attorney General in charge of the Criminal Division to perform the functions of the Designated Authority and also to delegate this authority. 28 CFR 0.64–6. This final rule delegates that authority to officials in the Criminal Division and OIA.

To address future agreements of this nature, this final rule applies to any executive agreement under 18 U.S.C. 2523 that either designates the Attorney General or the Department of Justice as the Designated Authority or authorizes the Attorney General to designate a Designated Authority (or like designation), and for which the Attorney General has designated the Criminal Division as such authority.

Administrative Procedure Act—5 U.S.C. 553

This rule is a rule of agency organization and relates to a matter relating to agency management and is therefore exempt from the requirements of prior notice and comment and a 30-day delay in the effective date. *See* 5 U.S.C. 553(a)(2), 553(b)(3)(A), 553(d).

Regulatory Flexibility Act

Further, a Regulatory Flexibility Analysis is not required to be prepared for this final rule because the Department was not required to publish a general notice of proposed rulemaking for this matter. 5 U.S.C. 604(a).

Executive Orders 12866 and 13563—Regulatory Review

This action has been drafted and reviewed in accordance with section 1(b) of Executive Order 12866, ''Regulatory Planning and Review,'' and section 1(b) of Executive Order 13563, ''Improving Regulation and Regulatory Review.'' This rule is limited to agency organization, management, and personnel as described in section 3(d)(3) of Executive Order 12866 and, therefore, is not a ''regulation'' or ''rule'' as defined by the order. Accordingly, this action has not been reviewed by the Office of Management and Budget.

Executive Order 13132—Federalism

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive Order 12988—Civil Justice Reform

This rule was drafted in accordance with the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Unfunded Mandates Reform Act of 1955

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector of $100,000,000 or more in any one year (adjusted annually for inflation), and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This action pertains to agency management, personnel, and organization and does not substantially affect the rights or obligations of non-agency parties and, accordingly, is not a ''rule'' as that term is used by the Congressional Review Act, 5 U.S.C. 804(3)(B), (C).

Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 28 CFR Part 0

International agreements, Treaties.

For the reasons stated in the preamble, part 0 of title 28 of the Code of Federal Regulations is amended as follows:

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

■ 1. The authority citation for part 0 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510, 515–519.

■ 2. Add Directive No. 2021–001 at the end of Appendix to Subpart K to read as follows:

Appendix to Subpart K of Part 0

Criminal Division

* * * * *

Directive No. 2021–001

Designated Authority under executive agreements on access to data by foreign governments.

By virtue of the authority vested in me by § 0.64–6 of Title 28 of the Code of Federal Regulations, I hereby delegate the authority to perform the functions of the Designated Authority under executive agreements between the United States of America and other countries regarding access to data by foreign governments, negotiated pursuant to the authority in 18 U.S.C. 2523, to the Deputy Assistant Attorneys General, Criminal Division, and the Director, the Deputy Directors and the Associate Director supervising implementation of such agreements in the Office of International Affairs. This delegation applies to executive agreements that either designate the Attorney General or the Department of Justice as the Designated Authority (or like designation) or authorize the Attorney General to designate a Designated Authority (or like designation), and for which the Attorney General has designated the Criminal Division as such authority.

Dated: October 7, 2021.

Kenneth A. Polite, Jr.,

Assistant Attorney General.

[FR Doc. 2021–25455 Filed 11–22–21; 8:45 am]

BILLING CODE 4410–14–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 381

[Docket No. 21–CRB–0011–PBR (2018–2022) COLA (2022)]

Cost of Living Adjustment to Public Broadcasters Compulsory License Royalty Rate

AGENCY: Copyright Royalty Board, Library of Congress.