amendment that was published in the Federal Register on July 1, 1997. The Commission adopted revisions to forms and schedules filed under the Securities Act of 1933, the Securities Exchange Act of 1934, related provisions of the Investment Company Act of 1940 and the Public Utility Holding Company Act of 1935, and the Trust Indenture Act of 1939, to eliminate the portion of those forms that requests filers who are natural persons to furnish their Social Security numbers. The 1997 amendment to Form MSD inadvertently omitted the removal of the second of two references to Social Security numbers in the instructions to the form.


FOR FURTHER INFORMATION CONTACT: Brice Prince, at (202) 551–5777, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: We are making a technical correction to Form MSD 1 under the Exchange Act.

List of Subjects in 17 CFR Part 249

Reporting and recordkeeping requirements, Securities.

Text of the Amendments

For the reasons set out above, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

1 1. The general authority citation for part 249 continues to read as follows:


2 2. Amend General Instruction M to Form MSD (referenced in § 249.1100), by removing the text ‘‘; social security numbers. The 1997 amendment to Form MSD inadvertently omitted the removal of the second of two references to Social Security numbers in the instructions to the form. 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, the person requests a classification under section 513(f)(2) of the FD&C Act.

Dated: January 24, 2018.

Brent J. Fields,
Secretary.

Federal Register / Vol. 83, No. 20 / Tuesday, January 30, 2018 / Rules and Regulations 4139
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 within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. 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 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(f), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

### TABLE 1—TEMPORARY CATHETER FOR EMBOLIC PROTECTION DURING TRANSCATHETER INTRACARDIAC PROCEDURES

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device failure leading to debris embolization and stroke or death ...............</td>
<td>Non-clinical performance testing, Animal testing, and Clinical performance testing.</td>
</tr>
<tr>
<td>Impeded or disrupted blood flow leading to peripheral ischemia ...................</td>
<td>Non-clinical performance testing, Animal testing, Clinical performance testing, and Labeling.</td>
</tr>
<tr>
<td>Device incompatibility with transcatheter intracardiac procedure device leading to prolonged treatment time or device failure.</td>
<td>Non-clinical performance testing, Animal testing, Clinical performance testing, and Labeling.</td>
</tr>
<tr>
<td>Adverse tissue reaction .............................................................................</td>
<td>Biocompatibility evaluation.</td>
</tr>
<tr>
<td>Infection .................................................................................................</td>
<td>Sterilization validation, Shelf life testing, and Labeling.</td>
</tr>
<tr>
<td>Vascular injury due to device delivery, deployment, placement, or retrieval.</td>
<td>Non-clinical performance testing, Animal testing, Clinical performance testing, and Labeling.</td>
</tr>
</tbody>
</table>

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 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. 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. 3501–3520). 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 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; 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 870

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 870 is amended as follows:

**PART 870—CARDIOVASCULAR DEVICES**

1. The authority citation for part 870 continues to read as follows:

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

2. Add § 870.1251 to subpart B to read as follows:
§ 870.1251 Temporary catheter for embolic protection during transcatheter intracardiac procedures.

(a) Identification. This device is a single use percutaneous catheter system that has (a) blood filter(s) at the distal end. This device is indicated for use while performing transcatheter intracardiac procedures. The device is used to filter blood in a manner that may prevent embolic material (thrombus/debris) from the transcatheter intracardiac procedure from traveling towards the cerebral circulation.

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

(1) 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) Simulated-use testing in a clinically relevant bench anatomic model to assess the following:

(A) Delivery, deployment, and retrieval, including quantifying deployment and retrieval forces, and procedural time; and

(B) Device compatibility and lack of interference with the transcatheter intracardiac procedure and device.

(ii) Tensile strengths of joints and components, tip flexibility, torque strength, torque response, and kink resistance.

(iii) Flow characteristics.

(A) The ability of the filter to not impede blood flow.

(B) The amount of time the filter can be deployed in position and/or retrieved from its location without disrupting blood flow.

(iv) Characterization and verification of all dimensions.

(2) Animal testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be assessed:

(i) Delivery, deployment, and retrieval, including quantifying procedural time.

(ii) Device compatibility and lack of interference with the transcatheter intracardiac procedure and device.

(iii) Flow characteristics.

(A) The ability of the filter to not impede blood flow.

(B) The amount of time the filter can be deployed in position and/or retrieved from its location without disrupting blood flow.

(iv) Gross pathology and histopathology assessing vascular injury and downstream embolization.

(3) All patient contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components intended to be provided sterile.

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

(6) Labeling for the device must include:

(i) Instructions for use;

(ii) Compatible transcatheter intracardiac procedure devices;

(iii) A detailed summary of the clinical testing conducted; and

(iv) A shelf life and storage conditions.

(7) Clinical performance testing must demonstrate:

(i) The ability to safely deliver, deploy, and remove the device;

(ii) The ability of the device to filter embolic material while not impeding blood flow;

(iii) Secure positioning and stability of the position throughout the transcatheter intracardiac procedure; and

(iv) Evaluation of all adverse events including death, stroke, and vascular injury.

Dated: January 24, 2018.

Leslie Kux,
Associate Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT:
Steven Elliott, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2565, Silver Spring, MD 20993–0002, 301–796–5285, steven.elliott@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the surgical smoke precipitator 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 reducing regulatory burdens 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(f)(1) of the FD&C Act (21 U.S.C. 360c(f)(1)) 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 and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

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...