September 24, 2024

Hobbs Medical, Inc.
John Kirwan
President
8 Spring St
Stafford Springs, Connecticut 06076

Re: K241874
Trade/Device Name: Aspiration Catheter (2189)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCX
Dated: June 28, 2024
Received: June 28, 2024

Dear John Kirwan:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241874

Device Name

Aspiration Catheter (2189)

Indications for Use *(Describe)*

To be utilized by a trained physician through a flexible endoscope for the collection of duodenal or jejunal fluids for diagnostic analysis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Prepared on: 2024-09-24

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Hobbs Medical Inc.
Applicant Address	8 Spring St Stafford Springs CT 06076 United States
Applicant Contact Telephone	860-684-5875
Applicant Contact	Mr. John Kirwan
Applicant Contact Email	jkirwan@hobbsmedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Aspiration Catheter (2189)
Common Name	Aspiration Catheter
Classification Name	Endoscope And Accessories
Regulation Number	876.1500
Product Code(s)	OCX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K844550	Hobbs Medical/Jayco Aspiration Catheter	OCX

Device Description Summary

21 CFR 807.92(a)(4)

The Hobbs Medical Aspiration Catheter is a sheath within a sheath design. The inner sheath is actuated using a proximal handle. The inner sheath is protected by an elastomeric membrane that has a slit at the distal end to allow for the inner sheath to advance. The inner sheath has three side holes at the distal tip for collection of aspirate. Once the sample is collected the inner sheath is retracted to protect the sample from contamination as it is withdrawn from the endoscope.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

To be utilized by a trained physician through a flexible endoscope for the collection of duodenal or jejunal fluids for diagnostic analysis.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended use and indications for use of the subject device are the same as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device and predicate device have the same intended use and are made from similar materials and technological features. The difference between the subject device and the predicate device is the subject device has an inner and outer sheath. The inner sheath is for collection of the sample which is retracted into the inner sheath during placement and after aspiration during device removal to prevent sample contamination. This difference does not raise new questions of safety and effectiveness. The subject device is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

To demonstrate that the Hobbs Aspiration Catheter has acceptable performance for its intended use and is substantially equivalent to the predicate device the following testing was performed:

- Joint integrity testing
- Deployment force testing
- Endoscope compatibility testing
- Design verification and validation to confirm the device performs as intended
- Protection of sample from contamination
- Shelf life testing performed in accordance with ASTM 4169, ASTM 4332, ASTM F2096, ASTM F88

The subject device testing demonstrates that the device is adequately robust, has acceptable performance characteristics for its intended purpose compared to the predicate device, and provides protection against sample contamination. This testing provides reasonable assurance that the subject device is safe and effective, and is substantially equivalent to the predicate device.

Not Applicable

In conclusion, all performance testing conducted demonstrated device performance and substantial equivalence to the predicate device.