June 3, 2024

Richard Wolf Medical Instruments Corporation
Mike McAndrew
US Head of Regulatory - QA/QC
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K231291
Trade/Device Name: Perforated Baskets
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: April 30, 2024
Received: May 1, 2024

Dear Mike McAndrew:

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.

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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical

and Infection Control 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.

510(k) Number *(if known)*
K231291

Device Name
Perforated Baskets

Indications for Use *(Describe)*
The products are used to store medical devices before, during, and after sterilization.
The products are intended to enable sterilization of the enclosed medical devices but are not intended to maintain sterility on their own; instead, they are used in conjunction with an FDA-approved sterilization wrap that is legally available on the market.
The products have no medical indications. Sterilization cycle times are as follow: Exposure time: 3 min
Temperature: 132 °C Drying time: 20 min

The maximum validated load weight for all devices listed below is 4.5 kg (approx. 9.92 lbs).

All measurements are in millimeter and are coded as follows [WidthxHeightxLength].

UNIVERSAL PERFORATED BASKET 1 (33001); 732x117x282)
UNIVERSAL PERFORATED BASKET 2 (33002); (743x200x282)
UNIVERSAL PERFORATED BASKET 3 (33003); (538x117x250)
UNIVERSAL PERFORATED BASKET 4 (33004); (538x117x250)
UNIVERSAL PERFORATED BASKET 5 (33005); (549x200x250)
PERFORATED BASKET FOR SMALL PARTS (33006); (128x40x121)
PERF. BASKET – KNEE ARTHROSC. BASIC SET (33007); (549x150x250)
PERF. BASKET – KNEE ARTHROSC. ACL/PCL 1 (33008); (549x150x250)
PERF. BASKET – KNEE ARTHROSC. ACL/PCL 2 (33009); (549x150x250)
PERF. BASKET FOR KNEE ARTHROSC. PREP TAB (33010); (549x150x250)
PERF. BASKET FOR VERTEBRIS LUMBAR (33011); (549x150x250)
PERF. BASKET FOR SHOULDER ARTHROSCOPY (33012); (538x117x250)
PERF. BASKET FOR VERTEBRIS FORAMINOTOMY (33013); (525x65x255)
PERF. BASKET FOR VERTEBRIS STENOSIS (33015); (549x150x250)
PERFORATED BASKET FOR CAMERA HEAD (38002); (448x73x200)
PERFORATED BASKET, UPPER URINARY TRACT 1 (38003); (635x75x132)
PERF. BASKET FOR CYSTOSCOPE/TELESCOPE (38004); (467x75x132)
PERFORATED BASKET FOR DISCOSCOPE (38005); (467x75x132)
PERFORATED BASKET FOR HYSTEROSCOPE 1 (38006); (467x75x132)
PERF. BASKET FOR VIDEO MEDIASTINOSCOPE (38007); (256x85x250)
PERFORATED BASKET FOR TELESCOPE (38008); (467x75x132)
PERFORATED BASKET FOR HYSTEROSCOPE 2 (38009); (467x90x132)
PERFORATED BASKET FOR STEREO TELESCOPE (38010); (477x139x196)
PERFORATED BASKET FOR NEPHROSCOPE (38011); (467x75x172)
PERFORATED BASKET FOR MORCESCOPE (38012); (467x75x172)
PERFORATED BASKET FOR CYSTO-URETHROSCOPE (38013); (451x64x80)
PERFORATED BASKET FOR 3D TELESCOPE (38014); (583x80x200)
PERF. BASKET FOR STANDARD TELESCOPE 1 (38015); (297x54x59)
PERF. BASKET FOR STANDARD TELESCOPE 2 (38016); (481x54x59)
PERF. BASKET FOR STANDARD TELESCOPE 3 (38017); (619x54x59)
PERFORATED BASKET FOR PAIN THERAPY (33014); (525x95x255)

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.

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K231291 510(k)

Summary

Submitter

Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, IL 60061

Phone:(847) 913 1113

Contact Person, Title: Mike McAndrew, US Head of Regulatory - QA/QC Date Prepared:05/30/2024

Legal Manufacturer

Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen, Germany

1. Devices

Device Trade Name	Device classification name	Regulation Number and Name	Product Code	Device Class	Review Panel
PERFORATED BASKETS	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories	880.6850 General Hospital	KCT	II	General Hospital

2. Predicate Device

Name of Predicate Device: KARL STORZ Metal Sterilization Trays

510(k) Number: K203198

Regulatory Class: II

Product Code: KCT

Manufacturer: Karl Storz Endoscopy America Inc

3. Device Description

3.1. Subject Device Identification

The PERFORATED BASKETS all have the same basic configuration, a metal basket base and a basket lid, with optional product specific instrument carriers (for multiple levels) or adapters and an additional basket for small parts. The base part and the lid of the PERFORATED BASKET are connected by a locking mechanism, which assures a tight connection of both parts.

3.2. Subject device characteristics

User

PERFORATED BASKETS are used for professional use only.

Delivered sterile / non-sterile

PERFORATED BASKETS are delivered in a non-sterile state.

Single use / reusable

PERFORATED BASKETS are reusable.

Software

PERFORATED BASKETS do not have software.

Materials with patient contact

PERFORATED BASKETS do not have direct or indirect contact with the patient.

4. Indications for Use

The products are used to store medical devices before, during, and after sterilization.

The products are intended to enable sterilization of the enclosed medical devices but are not intended to maintain sterility on their own; instead, they are used in conjunction with an FDA-approved sterilization wrap that is legally available on the market.

The products have no medical indications. Sterilization cycle times are as follow: Exposure time: 3 min Temperature: 132 °C Drying time: 20 min

The maximum validated load weight for all devices listed below is 4.5 kg (approx. 9.92 lbs).

All measurements are in millimeter and are coded as follows [WidthxHeightxLength].

UNIVERSAL PERFORATED BASKET 1 (33001); 732x117x282)
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PERFORATED BASKET FOR PAIN THERAPY (33014); (525x95x255)

5. Comparison of Technological Characteristics with the Predicate Device

The PERFORATED BASKETS are comparable to KARL STORZ Metal Sterilization Trays. Sterilization occurs through the perforated structure in the tray base and lid. After sterilization, the FDA cleared sterilization wrap maintains sterility. All of these characteristics are the same as the predicate device. The devices and the predicate have essentially the same indications for use and perform in a similar manner.

Item	Subject devices	Predicate devices	Explanation of differences
510(k) number	K231291	K203198	N/A
Manufacturer	Richard Wolf GmbH	Karl Storz Endoscopy America Inc	N/A
Product Code	KCT	KCT	None.
Regulation Number	880.6850	880.6850	None
Indications for Use	Perforated baskets The products are used to store medical devices before, during, and after sterilization. The products are intended to enable sterilization of the enclosed medical devices but are not intended to maintain sterility on their own; instead, they are used in conjunction with an FDA-approved sterilization wrap that is legally available on the market. The products have no medical indications. Sterilization cycle times are as follows: Exposure time: 3 min Temperature: 132 °C Drying time: 20 min The maximum validated load weight for all devices listed below is 4.5 kg (approx. 9.92 lbs). All measurements are in millimeter and are coded as follows [WidthxHeightxLength]. *Authors note: At this position corresponding devices and their dimensions are listed in every Instruction for use.*	The KARL STORZ Metal Sterilization Trays are intended only for use to encase and protect specific KARL STORZ reusable medical devices for sterilization in prevacuum steam sterilization cycles 132ºC for four minutes with a 20 minute dry time). When used in conjunction with an FDA cleared sterilization wrap, sterility of the enclosed medical device is maintained until used.	Similar.
Prescription/ over-the-counter-use	Prescription Use	Over the Counter	Different
Cleaning and Sterilization method for the basket	Devices must be reprocessed before the first usage.	Information not available	Different

Item	Subject devices	Predicate devices	Explanation of differences
Validated Sterilization Cycle	Pre-Vacuum Exposure time: 3 min, Temperature: 132°C	Pre-Vacuum Exposure time: 4min, Temperature: 132°C	Similar
Load condition	Maximum weight and loading conditions are either limited by the place holders for the intended devices if the submitted can hold more than one device, the loading template for specific instruments sets or the weight of the individual medical device if the submitted device is only intended to reprocess one item.	Maximum weight and loading conditions are either limited by the place holders for the intended devices if the predicate device can hold more than one device, the loading template for specific instruments sets or the weight of the individual medical device if the predicate device is only intended to reprocess one item.	Different
Maximum validated load weight	Up to 4.5 kg (approx. 9.92 lbs)	5 lbs	Different

6. Performed evaluation of impact of differences

The following testing was performed in order to support device performance. For each device it was evaluated whether specific testing was necessary. The following subsections present an overview including the decision whether specific testing was deemed necessary or not.

6.1. Cleaning and Sterilization

The devices are delivered in a non-sterile status. All devices need to be processed before each usage. Thus, the cleaning process was validated in compliance with the relevant standards and guidelines and the device was found to be suitable for the described procedures. A sterilization validation for the device was also conducted to validate their performance.

6.2. Performance Testing Bench

The performance of the devices in regards to their capability to be used for steam sterilization was tested. This sterilization process was validated in compliance with the relevant standards and guidelines and the device was found to be suitable for the described procedure.

Test	Test Method (Standard)	Acceptance Criteria	Results
Manual Cleaning	AAMI TIR 30: 2011, ANSI/ AAMI ST98: 2022	1: Visible soil: not visible 2: Protein/cm2 [µg/cm2]: < 6.4 µg/cm2 3: Hemoglobin [µg/cm2]: < 2.2 µg/cm2	1: passed 2: passed 3: passed
Steam Sterilization	EN ISO 14937, Annex D	Sterilization assurance level (SAL) > 10^{-6}	passed

7. Conclusion

The conclusions drawn from the nonclinical testing demonstrate the device in 510(k) K231291, the PERFORATED BASKETS, is as safe, as effective and performs as well, or better, than the legally market predicate device, cleared via 510(k) K203198.