October 9, 2024

HS Hospital Service SPA
% Guido Bonapace
Consultant
Isemed Srl
Via P. Togliatti, 19/X
Imola (BO), 40026
Italy

Re: K242029
Trade/Device Name: Trap Easy
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: July 3, 2024
Received: July 11, 2024

Dear Guido Bonapace:

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,

for Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2024.10.09 14:10:58 -04'00'

Jessica Carr
Assistant Director
DHT4A: Division of General 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.

Submission Number *(if known)*

K242029

Device Name

TRAP EASY

Indications for Use *(Describe)*

The device is used for drawing osteomedullary substance and/or for bone marrow explantation.

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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General Information

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Date prepared: 9th October, 2024

Device Name
Device Trade Name: TRAP EASY
Common Name: Gastroenterology-urology biopsy instrument
Classification name: Instrument, Biopsy
Regulation Number: 876.1075
Product Code: KNW

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name	Product code
K033616	TRAPMATIC SYSTEM SET	KNW

Device Description Summary

Trap Easy is a bone marrow biopsy needle, consisting of a cannula with cylindrical tip and ergonomic handle, a removable pyramidal stylet, a sample trapping device integrated into the cannula and an extraction wire.
The device is used for drawing osteomedullary substance and/or for bone marrow explantation.
This device is intended to be used only by experienced and properly trained physicians and is intended to be used exclusively for bone marrow tissue biopsies.
The device is available in different models:

- 8G x 100 mm
- 8G x 150 mm
- 11G x 100 mm
- 11G x 150 mm

Trap Easy is supplied in sterile packaging and is designed for single use, non-reusable. At the end of its use, the device should be disposed of as infectious hospital waste.

Intended use / Indications for Use

The device is used for drawing osteomedullary substance and/or for bone marrow explantation.

Indications for Use Comparison

Indications for use of subject device are the same of primary predicate device: the devices are intended to be used in the procedure for harvesting bone marrow specimens.

Both subject device and predicate devices are intended to be used by a physician.

Technological Comparison

The Trap Easy medical device has the same technological characteristics, design, material and principle of operation as predicate device Trapmatic System set (K033616). As a matter of facts, both the Trap Easy medical device and the Trapmatic System set consist of an outer cannula with handle and trapping element inside, and an extraction wire. As accessories, both devices possess a safety and luer lock cap.
Trap Easy medical device is characterized by the same principle of operation of primary predicate: both devices trap the sample inside and both devices are characterized by a safety and an activation mechanism of the trap. For the Trap Easy medical device, the safety is represented by the white button, while in the Trapmatic System, this safety feature is the white drawer. Then, to activate the mechanism, subject device is equipped with a lever on the side, while in the Trapmatic device, you need to push down the luer connector. Therefore, the only difference with the primary predicate consists in the safety feature that is present for the activation of the mechanism of action: in the Trap Easy this safety feature is represented by a white button, while in the Trapmatic System, it consists in a white drawer. The devices can therefore be considered substantially equivalent.
Subject device is available in sizes 8G and 11G, which fall within those available for the primary predicate device. In addition, the devices are made of the same materials: both consists of AISI 304 stainless steel cannula and ABS handle.
Both devices are manual instrument, provided for single-use and sterilized with Eto, therefore being substantially equivalent.

The devices can be considered substantially equivalent as the differences do not raise concerns about safety or effectiveness.

Non- Clinical and/or Clinical Tests Summary & Conclusions

Performance of subject device have been evaluated by testing sample integrity after biopsy, sample length of single biopsy, sample diameter, sample removal and by testing mechanical functioning of the needle.
The tests have been conducted in a manner as similar as possible to how the biopsy device is used in a medical procedure.
Performed tests show that all the 50 samples have a good integrity and there were no samples ruined or divided in small parts. Moreover, the sample removal was easy for all samples and the needles didn’t show any damages to the internal mechanism after all biopsies. The average lengths and diameters were compliant with acceptance criteria.

Obtained results demonstrated that the device's performances are maintained for the intended use of the device.
In addition, in order to guarantee performance and compliance, devices are subjected to inspections after the manufacturing process.
Nonclinical testing data demonstrate the technological characteristics of subject device Trap Easy and that the medical device perform as intended for its use.

The medical device Trap Easy is sterilized using Ethylene Oxide (EtO), and the sterilization process is validated in accordance with the requirements of ISO 11135:2014/A1:2018. The manufacturer, HS Hospital Service Spa, produces several sterile medical devices, all of which fall under the same process validation. These devices are categorized into four different families based on product type. The sterilization process has been validated and is periodically requalified to ensure the continued ability to effectively sterilize the products.
Additionally, the limits for Ethylene Oxide (EtO) residues and its by-products, Ethylene Glycol (EG) and Ethylene Chlorohydrin (ECH), are defined in accordance with ISO 10993-7, taking into account the limited exposure of the medical device.
Moreover, the Trap Easy medical device is available in two different packaging configurations that serve as the sterile barrier system for the product:

- A pouch made of Tyvek® 2FS and an OPA/PE film (16x44 cm)
- A blister made of Coated Tyvek® CR27 2FS and PET+PE600 (12x22.5 cm)

Both packaging configurations have been validated in compliance with the requirements of ISO 11607-1:2019.

Regarding the biocompatibility of the medical device, based on its characteristics, Trap Easy is classified according to Annex A of ISO 10993-1 as an externally communicating medical device with limited (< 24 hours) contact with bone/tissue. The material in direct contact is AISI 304 stainless steel, which is used for both the needle (cannula) and the mandrel (stylet). AISI 304 stainless steel is a well-established material, historically used in the manufacturing of this type of medical device due to its proven safety and performance.
Additionally, Trap Easy in its final finished form is identical to the Trapmatic System set in terms of formulation, processing, and sterilization, and no other chemical have been added.