DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 2, 2017

Maquet Critical Care Ab
% Mark Dinger
Senior Regulatory Affairs Specialist
Maquet Medical System USA
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K153688
Trade/Device Name: Edi Catheter ENFit
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories.
Regulatory Class: Class II
Product Code: PIF, CBK
Dated: January 30, 2017
Received: January 31, 2017

Dear Mark Dinger:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K153688

Device Name
Edi Catheter ENFit

Indications for Use *(Describe)*

The Edi catheter ENFit is intended for:

- Administrating nutrition, fluids and medications via the naso-gastro-enteric route
- Aspiration via the naso-gastroenteric route
- Transfers electrical activity (Edi signals) to compatible SERVO ventilator systems on which NAVA and NAVA NIV are available

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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**510(k) SUMMARY**
**as required by section 21 CFR 807.92**

Date prepared: March 1, 2017

**Submitter Name & Address**
Maquet Critical Care AB
Röntgenvägen 2
SE-171 54 Solna, Sweden
Tel: +46 10 335 73 00
Fax: +46 10 335 7838

Contact Persons for this submission:

Mirva Boothe
Regulatory Affairs Manager
Phone: +46 10 335 73 00
Email: mirva.boothe@getinge.com

Application Correspondent:

Mark Dinger
Senior Regulatory Affairs Specialist
Maquet Medical Systems USA
45 Barbour Pond Drive
Wayne, NJ 07470 USA
Email: mark.dinger@getinge.com
Phone: 973-709-7691
Fax: 973-909-9954

**Trade name**

| |
|---|
| Edi Catheter ENFit |

**Device Classification**

| *Common Name* | *Classification Product Code* | *Class* | *Regulation Number* |
|---|---|---|---|
| Gastrointestinal tubes with enteral specific connectors | PIF | II | 21 CFR 876.5980 |
| Ventilator, continuous, facility use | CBK | II | 2l CFR 868.5895 |

**Predicate Device Identification**

| *Legally marketed devices to which equivalence is being claimed* | *510(k) #* |
|---|---|
| SERVO-i Ventilator System | K123149 |

## Device Description

The Edi Catheter ENFit is a sterile, single use nasogastric feeding tube that carries electrode rings that record diaphragm electrical activity (Edi signal). The Edi Catheter ENFit is an accessory to be used with patients in the range of neonates, infants, and adults together with the SERVO ventilator system. The Edi signal is used as an additional detector to improve the synchrony between the patient and the ventilator and to give the patient corresponding ventilatory support in the ventilation modes NAVA and NIV NAVA.

As a nasogastric feeding tube, the Edi Catheter ENFit is used for administration of nutrition, fluids and medications, as well as and aspiration via the naso-gastroenteric route. For the 12 Fr and 16 Fr catheters, a sump lumen is available for air venting the feeding tube to the atmosphere.
The new ENFit connector which is compliant with ISO 80369-3 is introduced in order to avoid misconnections with small-bore connectors used for other healthcare applications than enteral feeding.

See table 1 below for a listing of the main components and characteristics of the device, compared to the predicate device.

*Table 1. Comparison with predicate device catheter*

| | **Predicate device** | **Current device** | **Comment** |
|---|---|---|---|
| **Technology** | | | |
| Device type | Nasogastric feeding tube | Nasogastric feeding tube | Identical |

| | | | |
|---|---|---|---|
| Measurement method | Monitor electrical signal from diaphragm activity (Edi) | Monitor electrical signal from diaphragm activity (Edi) | Identical |
| Energy source | From NAVA module in SERVO Ventilator System | From NAVA module in SERVO Ventilator System | Identical |
| Patient group | Neonatal to adult | Neonatal to adult | Identical |
| **Components/Parts** | | | |
| Total number of electrodes | 10 | 10 | Identical |
| Electrodes | Material: Stainless steel | Material: Stainless steel | Identical |
| Electrical connector | 14 pole circular connector | 14 pole circular connector | Identical |
| Feeding tube | Material: PUR | Material: PUR | Identical |
| Feeding connector | Funnel type<br>Material: PVC | ENFit type<br>Material: ABS | New type of connector and new material for current device |
| Sump lumen | For 12 and 16 Fr | For 12 and 16 Fr | Identical |
| Catheter dimensions | Length:<br>49-125 cm<br>Diameter:<br>6 / 8 / 12 / 16 Fr | Length:<br>49-125 cm<br>Diameter:<br>6 / 8 / 12 / 16 Fr | Identical size range. Additional feeding holes and one new design option for current device:<br>8 Fr 50 cm |
| **Sterilization** | | | |
| Sterile barrier system | Preformed pouch | Preformed pouch | Identical |
| Sterilization | Gamma sterilization | Gamma sterilization | Identical |
| **Accessories** | | | |
| Guidewire | For 6 Fr 49 and 50 cm<br>For 8 Fr 100 cm<br>For 8 Fr 125 cm | For 6 Fr 49 and 50 cm<br>For 8 Fr 100 cm<br>For 8 Fr 125 cm | Not part of device. Guidewire cleared in K153461, is not a device component. |

## Indications for Use

The Edi catheter ENFit is intended for:

- Administrating nutrition, fluids and medications via the naso-gastro-enteric route
- Aspiration via the naso-gastroenteric route
- Transfers electrical activity (Edi signals) to compatible SERVO ventilator systems on which NAVA and NAVA NIV are available

## Comparison of Indications for Use

The Indications for Use for the subject device is comparable to the Indications for Use for the predicate device Edi Catheter PHT Free, which is an accessory within the ventilator system SERVO-i (K123149).

However, since the proposed device is submitted as a product of its own right instead of an accessory within the ventilator system, the Indications for Use is not the same as the Indications for Use for the entire ventilator system.

The predicate device Edi Catheter PHT Free has been cleared with the ventilators Indications for Use. The Indication for Use for the Edi catheter ENFit has been clarified compared to the Edi catheter PHT Free. The following information has been updated, which is also relevant for the predicate device Edi catheter PHT Free.

- Added:
    - Aspiration via the naso-gastroenteric route
- Clarified:
    - Transfers electrical activity (Edi signals) to compatible SERVO ventilator systems on which NAVA and NAVA NIV are available

## Summary of Technological characteristics

The technological characteristics of the subject device Edi catheter ENFit with respect to design, material and energy source are similar to the Edi catheter PHT free included in the predicate device (K123149), see summary and comparison below. Note that the differences listed here are the only differences between the catheter variants.

**Design**

The design of the catheters and methodology used for fulfilling its intended use is the same between the subject and predicate device. The only differences include:

- A **new male ENFit connector** on the feeding tube, in order to avoid misconnections with other small-bore connectors used for other applications than enteral feeding. This update is done according to the Standard requirements, ISO 80369-3:2016: Small-bore connectors for liquids and gases in healthcare applications -- Part 3: Connectors for enteral applications
- **Addition of a new size option** within the current size range (Edi Catheter ENFit 8Fr/50cm). This particular size combination is new, although the predicate device includes catheters 8Fr/X cm and XFr/50 cm. The design of of the catheter is therefore considered the same.
- Additional **feeding holes** to facilitate feeding and aspiration.

**Material**

The catheter material remains identical between the catheters, except from:

- The new ENFit connector contains a **new material** compared to the predicate device (ABS in ENFit connecter and PVC in predicate device). The new material has been tested for biocompatibility according to applicable sub-standards of ISO 10993-1:2009.

However, the material coming in direct contact with the patient is identical between the subject and predicate device.

**Energy source**

Identical. From NAVA module in SERVO Ventilator System.

## Non-clinical Testing

- Biocompatibility testing in conformance to "ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" and applicable sub-standards has demonstrated the biological safety of all parts of the proposed feeding tubes that have contact with the patient.
- Stability testing evaluated the properties of the proposed feeding tubes after accelerated aging in support of the product expiration date.
- The risks associated with the misconnection of the ENFit connector and feeding/aspiration have been assessed.
- Verification of the proposed ENFit Connector includes the tests listed below, in accordance with ISO 80369-3, Small- bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications, using the test methods provided in ISO 80369-20, Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods.
    - Fluid Leakage
    - Stress Cracking
    - Resistance to separation from axial load
    - Resistance to separation from unscrewing
    - Resistance to overriding
    - Disconnection by unscrewing
- Evaluation of the Usability validation for the new ENFit connector.

Verification activities have been performed for all changes that have been updated due to the changes performed in this submission. The testing demonstrates that the proposed device conform to all requirements of the Edi Catheter ENFit.

## Animal Testing

Animal testing was not relied upon for the determination of substantial equivalence to the predicate device.

## Clinical Investigation

Clinical evaluations were not relied upon for the determination of substantial equivalence to the predicate device based on the device classification, sufficient data and functional performance information provided in the submission.

## Conclusion

There are no different questions regarding safety and effectiveness for the Edi Catheter ENFit compared to the predicate device Edi Catheter PHT Free within the SERVO-i ventilator system (K123149).

MAQUET has conducted the risk analysis and performed the necessary verification and validation activities to demonstrate that the design outputs meet the design input requirements and the appropriate product standards.

MAQUET has concluded that the subject device, Edi Catheter ENFit is substantially equivalent to the predicate device, Edi Catheter PHT Free which is an accessory within the SERVO-i ventilator system (K123149).