DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 11, 2015

Maquet Critical Care AB
% Linda Slutzky
Regulatory Affairs Specialist II
Maquet Medical Systems USA
45 Barbour Pond Drive
Wayne, NJ 07470

Re: K153461
Trade/Device Name: Guide wire for Edi Catheter
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: November 30, 2015
Received: December 1, 2015

Dear Linda Slutzky,

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K153461

Device Name
Guide wire for Edi Catheter

Indications for Use *(Describe)*

The guide wire is intended to be used as a stylet inserted into the MAQUET Edi Catheter to stiffen it in order to simplify its placement in the intended patient population comprising adult, pediatric, infant and neonatal patients.

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.

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510(K) SUMMARY
(As required by section 807.92(c))

510(k) prepared November 26, 2015

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Trade name

Guide wire for Edi Catheter

Device Classification

Common Name	**Classification Product Code**	**Class**	**Regulation Number**
Catheter placement stylet	KNT	II	21 CFR 876.5980

Predicate Device Information

Legally marketed devices to which equivalence is being claimed	**510(k) #**
Guide wire for Edi Catheter	K101199

Indication for use:
The guide wire is intended to be used as a stylet inserted into the Maquet Edi Catheter to stiffen it in order to simplify its placement in the intended patient population comprising adult, pediatric, infant and neonatal patients.

General Description
The function of the Guide wire for Edi Catheters is to provide the necessary stiffness to facilitate the clinicians in the placement of the Maquet Critical Care AB naso-gastric feeding tube called Edi Catheter. The guide wire is inserted as a stylet into the feeding lumen of the Edi catheter prior to insertion of the Edi catheter in the patient and is removed right after the placement of the Edi catheter is completed.

The Guide wire for Edi Catheter consists of symmetrical stainless steel wire surrounded by a spiral stainless steel wire which is PTFE (polytetrafluoro-ethylene) coated. It also has soft and rounded ends. A safety ribbon runs thru the length of the Guide wire and is welded at each end to contain the coil of the spring. The Guide wire for Edi Catheter is provided in a non-sterile package and is for single use only. The individually packed Guide wires are delivered to the customer in an outer plastic bag containing five (5) Guide wires.

Changes from the previous notification
The predicate device´s coating was manufactured with a processing aid containing a low level of PFOA (Perfluorooctanoic acid) used in the polymerization of the coating. The processing aid should not be present in the finished coating of the predicate device since the PFOA is completely dissipated at the point the coating is cured.

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The change in this submission is that the PFOA is removed from the manufacturing process for the coating of the subject device. This change is performed due to that the processing aid PFOA has been mandated by the US government (EPA) to be removed from industrial use.

Non-clinical testing and performance
The following biocompatibility tests has been performed according to Annex A in ISO 10993-1 and Attachment A in ODE General Program Memorandum #G95-1:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity

Other functional verification activities performed are;

- Fracture and Flex testing
- Corrosion resistance
- Particulate matter

Comparison of the intended use
The intended use for the subject device is identical with the intended use of the predicate device.

Comparison of the technology used
The Guide wire for Edi Catheter has the same technical specifications and performance as the cleared Guide wire for Edi Catheters, K101199. The only difference is the updated coating process.

Conclusion
Maquet Critical Care AB believes that the subject Guide wire for Edi Catheter is substantially equivalent to the predicate Guide wire for Edi Catheters in application K101199 regarding the intended use of the device, the indication for use and the fundamental technology of the device.