K101199

MAQUET
GETINGE GROUP

510(k) Summary

Summary as required by section 807.92

Date of preparation: August 26th 2010

Sponsor/Manufacturer: MAQUET Critical Care AB
Röntgenvägen 2
SE-171 54, Solna, Sweden

AUG 27 2010

Contact person for this Submission: Gunilla Lidin
Direct phone: (011) 46 8 730 79 58
gunilla.lidin@maquet.com

U.S. Contact Person: Whitney G. Törning
Director of Regulatory Affairs
MAQUET, Inc.
45 Barbour Pond Drive
Wayne, NJ 07470
Phone: 973.709.7994
Fax: 973.709.7016
whitney.torning@MAQUET.com

Trade name	Model	Model number
Guide wire for Edi Catheter	For 6 French neonate/infant Edi Catheter	66 71 270
Guide wire for Edi Catheter	For 8 French pediatric Edi Catheter	66 71 272
Guide wire for Edi Catheter	For 8 French adult Edi Catheter	66 71 292

* Note - The terms "stylet" and "guide wire" are to be considered interchangeable.

Common Name	Classification Number	Class	Regulation Number
Catheter Placement Stylet	KNT	II	21 CFR 876.5980

Device description including technological characteristics

The function of the Guide wire for Edi Catheter is to provide the necessary stiffness to facilitate the clinician in the placement of the MAQUET naso-gastric feeding tube called Edi Catheter. The guide wire is inserted as a stylet into the feeding lumen of the 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 PFTE (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.

MAQUET
GETINGE GROUP

Indications 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.

Predicate Devices
The Guide wire for Edi Catheter is substantially equivalent in intended use, indications, technological characteristics and principles of operations as the following devices.

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
FEEDING TUBE PLACEMENT STYLET (BIOSEARCH MEDICAL PRODUCTS, INC)	K831840
PEDI-TUBE(R) STYLET (BIOSEARCH MEDICAL PRODUCTS, INC)	K894857
KANGAROO FEEDING TUBE PLACMENT STYLET (SHERWOOD MEDICAL CO)	K960632
GUIDE WIRE, VARIOUS TYPES (ACME-MONACO CORP) (material & design only)	K920884

Substantial Equivalence Conclusion

- The indications for use are SE with Biosearch Medical Product's stylets (K831840 & K894857) and Sherwood Medical stylet (K960632). Since the Edi Catheter is a naso-gastric feeding tube, the Guide wire for Edi Catheter is intended to stiffen the catheter in order to simplify catheter placement.
- The Guide wire of Edi Catheter's indication for use is different compared to the identical AMCE Monaco Guide wire K920884 since their device is intended for cardiovascular use. Maquet Critical Care AB believes that using our Guide wire during placement of a naso gastric feeding tube is associated with less risk than using the identical device in the cardiovascular system, with regards to operation time, mechanical strain and biocompatibility considerations.
- The Guide wire function is SE to Biosearch Medical Product's stylets (K831840 & K894857) and Sherwood Medical stylet (K960632).
- The Guide wire basic design is SE to AMCE Monaco Guide wire K920884, Biosearch Medical Product's stylets (K831840 & K894857) and Sherwood Medical stylet (K960632).
- The Guide wire's material (Stainless steel) is SE with Biosearch Medical Product's stylets (K831840 & K894857) and Sherwood Medical stylet (K960632). Stainless steel has been used on market in this application for almost 30 years.
- The Guide wire's material (PTFE- Polytetrafluoro Ethylene) is SE with ACME Monaco Corp. Guide wire K920884. PTFE- Polytetrafluoro Ethylene is a well known coating and has been used in medical devices for 40 years.

Performance testing
The Guide wire for Edi Catheter has been subjected to performance testing which included: mechanical strain, biocompatibility, physical properties and animal testing. These tests have demonstrated that the device is as safe and as effective as the predicate legally marked devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAQUET Critical Care AB
% Ms. Whitney Torning
Director, Regulatory Affairs
MAQUET Cardiovascular
45 Barbour Pond Drive
WAYNE NJ 07470

AUG 27 2010

Re: K101199
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: August 13, 2010
Received: August 18, 2010

Dear Ms. Torning:

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.

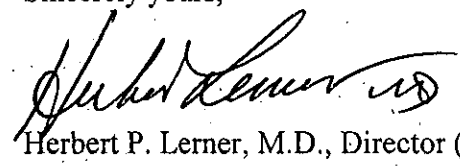
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101199

MAQUET
GETINGE GROUP

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K101199

Device Name: Guide wire for Edi Catheter

Indications 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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K101199