K102532

FEB 25 2011

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510 (K) Summary [as required by 21 CFR 807.92(c)]

Submitter: Maquet Cardiopulmonary AG
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Date Prepared: August 31, 2010

Device Trade Name: HLS Cannula non-coated, with BIOLINE Coating and with SOFTLINE Coating

Common/Usual name: HLS Femoral Cannula

Classification names: Catheter, Cannulae and Tubing, Vascular,
Cardiopulmonary Bypass

Predicate Devices:

Bio-Medicus Femoral Cannula, Medtronic USA, cleared under K924642,

QUADROX-i Adult Microporous Membrane Oxygenator with and without Arterial Filter with SOFTLINE Coating, MAQUET Cardiopulmonary AG, cleared under K082117,

QUADROX-i Adult Microporous Membrane Oxygenator with and without Arterial Filter with BIOLINE Coating, MAQUET Cardiopulmonary AG, cleared under K090511.

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Device Description:

The HLS Cannula from MAQUET is a wire-reinforced, thin-wall cannula made of polyurethane. The transparent proximal section has no reinforcement and can be clamped. Each cannula is supplied with a pre-mounted 3/8" connector and an introducer that allows a guide wire up to 0.038" to be inserted. The cannula is available with an optional percutaneous insertion kit for the Seldinger technique and an optional BIOLINE or SOFTLINE Coating. The HLS Cannula comes in a range of sizes and lengths.

The HLS Cannula is a sterile and non-pyrogenic device, for single use only and is not to be re-sterilized by the user.

The insertion kit from MAQUET comprises various components which permit access to the vessel. One insertion kit is available for the arterial cannula (PIK 100) and one for the venous cannula (PIK 150).

Indications for Use:

The HLS Cannula from MAQUET is intended for use by trained physicians only. The HLS Cannula may be utilized to cannulate suitable vessels to provide circulatory perfusion of organs and vessels by forming a connection with the extracorporeal circulation. Standard surgical or percutaneous insertion techniques can be employed. This product is intended for use up to six hours or less.

The insertion kit is used for preparing the cannulation of vessels for extracorporeal circulation. Surgical procedures can be performed under visual control or with percutaneous cannulation using the Seldinger technique.

Statement of Technical Comparison:

HLS Cannula non-coated, with BIOLINE Coating and with SOFTLINE Coating from MAQUET Cardiopulmonary AG, have a comparable intended use as the Bio-Medicus Femoral Cannulae (K924642). Both are intended to be used to cannulate vessels, perfuse vessels or organs up to 6 hours. Standard surgical or percutaneous insertion techniques can be used.
Furtheron the indications for use of the SOFTLINE Coating of the QUADROX-i Adult with SOFTLINE Coating is the same as with the HLS Cannula with SOFTLINE Coating and the indications for use of the BIOLINE Coating of the QUADROX-i Adult with BIOLINE Coating is the same as with the HLS Cannula with BIOLINE Coating.
The HLS Cannulae from MAQUET have similar technical characteristics, performance specification and materials as the predicate devices.

Both cannulae are made of polyurethane and are protected from kinking – to a greater or lesser extent – by wire reinforcement. The standard adult sizes are equipped with 3/8" connectors; all feature a designated clamping section.

Non-clinical Testing:

Performance testing has resulted in data that demonstrate that the HLS Cannulae performs according to the applied performance standards. The following performance characteristics of the HLS Cannulae were compared with the predicate device to determine substantial equivalence:

Evaluation of flow rate
For a relevant flow of 0 – 6 liters /minute the pressure drop of arterial and venous HLS Cannulae was measured in comparison to the predicate devices Bio-Medicus Femoral Cannulae from Medtronic.
The performance data of MAQUET cannulae as compared to the MEDTRONIC predicate cannulae are substantially equivalent.

To evaluate the safety and effectiveness of the HLS Cannula additional testing was performed:

Kink resistance
This test is to verify that the wire re-inforced cannulae shafts will not kink.

Tensile test of connection of cannula-connector
This test is to verify the bonding stability between cannulae and connector.

Tensile test of connection of introducer grip
This test is a verification of bonding of introducer and grip.

Verification of six hours pressure resistance
This test is to verify the durability of all connections of HLS arterial and venous Cannulae for a period of 6 hours at 1.5 bar.

Air tightness
This test is to verify that all connections of the cannulae are air-tight if put to a specified vacuum.

Evaluation of Corrosion
This test is to evaluate if cannulae corrode.

Evaluation on printed depth-markings of cannulae
The test is to verify that the adhesion of the printing is sufficient.

The HLS Cannulae non coated, with BIOLINE Coating and with SOFTLINE Coating have been tested or evaluated for compliance to ISO 10993-1 Biologic Evaluation of Medical Devices as well as to ISO 10555-1 "Sterile, single-use intravascular catheters - Part 1 general requirements". The products met these requirements.

Determination of Substantial Equivalence

MAQUET Cardiopulmonary AG has considered indications for use, design, materials, performance characteristics, and safety and effectiveness of the proposed HLS Cannulae non-coated, with BIOLINE Coating and with SOFTLINE Coating as compared to the predicate devices.
Based on the review and testing provided in this submission MAQUET Cardiopulmonary AG believes that the HLS Cannula non-coated, with BIOLINE Coating and with SOFTLINE Coating is substantially equivalent to the named predicate devices that are FDA cleared.

Conclusion

The HLS Cannulae non coated, with BIOLINE Coating and with SOFTLINE Coating are substantially equivalent to the named predicate devices which currently hold market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Maquet Cardiopulmonary AG
Whitney Torning
Director of Regulatory Affairs
45 Barbour Pond Drive
Wayne, NJ 07470

FEB 25 2011

Re: K102532
Trade Name: HLS Cannula Non-coated, with BIOLINE Coating, and with SOFTLINE Coating
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: January 28, 2011
Received: February 2, 2011

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102532

Device Name: HLS Cannula

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K102532