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510 (k) Summary
[As required by 21 CFR 807.92(c)]

Date:	June 5th 2013
Submitter:	MAQUET Cardiopulmonary AG Kehler Straße 31 76437 Rastatt Germany
Contact Person:	Sarah Betz Manager Regulatory Affairs Phone: +49 7478 921-440 Fax: +49 7478 921-8667 E-mail: sarah.betz@maquet.com
Device Trade Name:	Arterial HLS Cannula 13 Fr non-coated, with BIOLINE Coating and with SOFTLINE Coating
Common/Usual name:	HLS Cannula
Classification Name:	Catheter, Cannulae and Tubing, Vascular, Cardiopulmonary Bypass (21 CFR 870.4210, DWF)

Predicate Devices:

K102532 HLS Cannula 15-29 Fr, MAQUET Cardiopulmonary AG, Germany

K924642 Bio-Medicus One Piece Femoral Arterial Cannula 12 Fr, Medtronic, USA

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 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 vessels. One insertion kit is available for the arterial cannula (PIK 100) with a length of 100 cm and one for the venous cannula (PIK 150) with a length of 150 cm.

Additionally as accessories to the percutaneous insertion kit, there are two sets with further dilatators available. One set with larger dual step dilatators (18 / 20, 20 / 22, 22 / 24 Fr) for a better vessel dilation in the cases where cannulae are used bigger than 23 Fr. One set contains a smaller dilatator (8 / 10 Fr), dedicated for the insertion of the smaller cannulae like 13 Fr. As further accessories are separately guidewire sets available. These guidewire sets consist of five separately packed guidewires (lengths 100 or 150 cm) which are the identic articles as used in the Percutaneous Insertion Kit itself.

Intended 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.

Technological Characteristics:

The Arterial HLS Cannula 13 Fr is substantially equivalent to the previously cleared HLS Cannula 15-29 Fr (K102532). The modification only consists of the addition of a smaller diameter. They have the same intended use, the materials used are equivalent and the design is similar. Also function and handling is comparable.

The Arterial HLS Cannula 13 Fr is comparable to the Bio-Medicus One Piece Femoral Arterial Cannula 12 Fr from Medtronic (K924642). Both are intended to be used to cannulate vessels, perfuse vessels or organs in a cardiopulmonary bypass. Standard surgical or percutaneous insertion techniques can be used. Both cannulae are made of polyurethane and are protected from kinking – to a greater or lesser extent – by wire reinforcement.

Non-clinical Tests:

Testing and evaluation on safety and effectiveness was conducted to demonstrate that the Arterial HLS Cannula 13 Fr is substantially equivalent to the existing HLS Cannulae 15-28 Fr (K102532) from MAQUET and to the Bio-Medicus One Piece Femoral Arterial Cannula 12 Fr from Medtronic (K924642).

Substantial equivalence testing performed and presented in the original HLS Cannula 510(k) is applicable for the devices included in this submission. These tests included Biocompatibility, Packaging and Sterility.

The modified devices were subjected to additional testing based on the Risk Analysis performed relative to the modifications made to the design. Additional testing included Flow Rate, Kink resistance, Pressure resistance, Integrity and Tensile tests.

Clinical Tests:

Clinical results are not required for this submission to support substantial equivalence.

Conclusion:

The Arterial HLS Cannula 13 Fr submitted in this Special 510(k) Premarket Notification has essentially the same intended use, design / technological and performance characteristics as the predicate devices. The results of all testing demonstrate that the Arterial HLS Cannula 13 Fr is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 5, 2013

Maquet Cardiopulmonary AG
c/o Sarah Betz
Neue Rottenburger Str. 37
Hechingen, Germany 72379

Re: K131666
Trade/Device Name: Arterial HLS Cannula 13 Fr. non-coated, with Bioline coating and 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: June 5, 2013
Received: June 7, 2013

Dear Ms. Betz:

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 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. 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,

Kenneth J.
Cavanaugh -S

for Bram D. Zuckerman, Ph.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): K131666

Device Name: Arterial HLS Cannula 13 Fr non-coated, with BIOLINE Coating and with SOFTLINE Coating

Indications for Use:

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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)

Kenneth J. Cavanaugh -S