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510(k) Summary

[as required by 21 CFR 807.92(c)]

Submitter	**MAQUET Cardiopulmonary AG** Kehler Strasse 31 76437 Rastatt Germany
Contact Person	Dr. Ingrid Richter Phone: 011 49 7478 921 337 Fax: 011 49 7478 921 8667 e-mail: ingrid.richter@maquet.com
Date Prepared	October 19, 2012
Device Trade Name	**Hemoconcentrators : BC 60 plus, BC 140 plus**
Common/Usual Name	Hemoconcentrator
Classification Names	High Permeability Hemodialysis System Hemoconcentrator *(21 CFR 876.5860 – Product Code: KDI)*
Predicate Devices	Hemocor HPH® 700, Minntech Corp. USA, K983085 Hemocor HPH® 1400, Minntech Corp. USA, K923139

Device Description

BC 60 plus, BC 140 plus Hemoconcentrators are used to remove excess fluid from the blood during and/or following cardiopulmonary bypass procedures. Hemoconcentrators are ready for use after they have been filled and vented as the membrane contains no stabilizers. The type of Hemoconcentrator used is determined by the protocol used.

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Indications for Use

The MAQUET Hemoconcentrators are used to remove excess fluid from the blood or to concentrate highly diluted blood solutions. They are only intended for use for blood concentration during and/or following cardiopulmonary bypass procedures.
The maximum duration of use is 6 hours.
The physician in charge of treatment has sole responsibility for decisions concerning use of the hemoconcentrator.

Statement of Technical Comparison

The Hemoconcentrators, BC 60 plus, BC 140 plus are comparable to the Hemocor HPH® 700 K983085, Hemocor HPH® 1400 K923139 from Minntech Corp. USA, regarding the principals of operation, performance and indications for use.

Non-clinical Testing

The Hemoconcentrators BC 60 plus and BC 140 plus have been tested to and met the requirements of ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing as well as the requirements of ISO 8637 Cardiovascular implants and extracorporeal systems – Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators.

Determination of Substantial Equivalence

Evaluation and testing on safety and effectiveness was executed to demonstrate that the Hemoconcentrators BC 60 plus, BC 140 plus described in this submission are substantially equivalent to the Hemocor HPH® 700 (K983085), Hemocor HPH® 1400 (K923139) from Minntech Corp., USA.

The following areas have been tested and / or evaluated:

- Integrity
- Performance
- Biocompatibility
- Sterility

Conclusion

The data given demonstrate that the Hemoconcentrator BC 60 plus and BC 140 plus are substantially equivalent to the named predicate devices which have FDA market clearance.

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

June 26, 2013

MAQUET Cardiopulmonary AG
% Ms. Ingrid Richter
Regulatory Affairs Manager
Kehler Strasse 31
RASTATT 76437
GERMANY

Re: K123288
Trade/Device Name: BC 60 plus, BC 140 plus Hemoconcentrator
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: May 17, 2013
Received: May 20, 2013

Dear Ms. Richter:

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 -S

for

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

Indications for Use

510(k) Number (If known): K123288

Device Name:

BC 60 plus, BC 140 plus Hemoconcentrator

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)

Herbert P. Lerner -S