MAQUET
GETINGE GROUP

APR 1 1 2013

Short Port Blunt Tip Trocar
510(k) Summary
Prepared in accordance with 21 CFR Part 807.92

510(k) Number:	K130121
Date Prepared:	8 April 2013
Device Owner:	MAQUET Cardiovascular LLC 45 Barbour Pond Drive Wayne, New Jersey 07470
Contact Personnel:	Mark Dinger
Title:	Regulatory Affairs Specialist II
Email:	mark.dinger@maquet.com
Phone:	973-709-7691 **Fax:** 973-807-1658
Trade Name:	Short Port Blunt Tip Trocar
Device Generic Name:	Trocar Port
Primary Classification:	According to 21 CFR 876.1500 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Primary Product Code GCJ, and Secondary Product Code GEI.
Predicate Device:	K992353 Blunt Tip Trocar Port (SE: 30 July 1999)
Device Description:	The Short Port Blunt Tip Trocar (BTT) is used to provide a port of access for insertion of endoscopic instruments into an incision site. The device consists of a main body with a Balloon on the distal end, a Balloon inflation port, an Endoscope seal on the proximal end, and an external port with a one-way valve for gas insufflation. It also includes a Cannula seal to allow insertion of the Harvesting Cannula. The balloon minimizes leakage and secures the port. A 30 cc syringe is provided for inflation/deflation of the Balloon.
Indications for Use:	This product has applications for surgery in the saphenous vein, or radial artery for establishment of a port of entry for endoscopic instruments.

Technological Characteristics

The Proposed Short Port Blunt Tip Trocar and the predicate devices have the following similarities:

- the same intended use,
- the same operating principles,
- sterilized using the same materials and processes,
- has same packaging.

The Proposed Short Port Blunt Tip Trocar and the predicate devices have the following differences:

- Material change: From Latex balloon.
- Labeling change: Revision of Latex content statement.
- Change converter door to Cannula Seal and 7mm Seal.

This difference is not considered a technological difference and is substantially equivalent to the predicate devices.

Safety and Performance:

MAQUET Cardiovascular's development process required that the following activities be completed during the development of the Short Port BTT:

- Performance testing
- Biocompatibility testing
- Sterility testing
- Shelf life testing

The results of the in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the currently marketed Short Port BTT.

Conclusion:

Based upon the information submitted in this Traditional 510(k) premarket notification, MAQUET's Short Port BTT is substantially equivalent to the currently marketed Short Port BTT. The Short Port BTT is similar to the predicate devices in the intended use and the fundamental scientific technology of the device. The design verification and validation testing established that the Short Port BTT is substantially equivalent as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

MAQUET Cardiovascular LLC
% Mr. Mark Dinger
Regulatory Affairs Specialist II
45 Barbour Pond Drive
Wayne, New Jersey 07470

April 11, 2013

Re: K130121
Trade/Device Name: Short Port Blunt Tip Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 21, 2013
Received: March 27, 2013

Dear Mr. Dinger:

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, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130121

Device Name: Short Port Blunt Tip Trocar (BTT)

Indications For Use:

This product has applications for surgery in the saphenous vein, or radial artery for establishment of a port of entry for endoscopic instruments.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

_____ For

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K130121