K082725

510(k) SUMMARY

DEC 17 2008

Submitter	MAQUET Cardiovascular
Submitter's Address	170 Baytech Road San Jose, CA 95134
Telephone	(408) 635-6824
Fax	(408) 635-3907
Contact Person	Christina L. Rowe
Date Prepared	September 16, 2008
Device Trade Name	VASOSHIELD Pressure Controlling Syringe
Device Common Name	Distention and irrigation syringe
Device Classification Name	Introduction/drainage catheter and accessories
Device Classification	Class II
Summary of substantial equivalence	The design, materials, method of delivery, features, and intended use of the VASOSHIELD Pressure Controlling Syringe are substantially equivalent to the predicate devices: InPress Syringe, (K043515, cleared on March 31, 2005), the DMC Saphenous Vein System (K000704, cleared on May 19, 2000), and the DLP Pressure Sensing Syringe (K853586, cleared on November 14, 1985).
Device description	The VASOSHIELD Pressure Controlling Syringe is identical to the InPress Syringe in design, materials, principles of operation, and manufacturing process. The syringe is comprised of 10 biocompatible components including a syringe, a syringe stopper, ball, stainless steel pin, spring and rod, green acetal ring, black acetal pusher, a white acetal knob and body. The syringe has three predetermined pressure settings of 150 mm Hg, 250 mm Hg, and 350 mm Hg. The syringe is a single use device, supplied sterile.
Indications for Use	The device is indicated for controlling pressure during the preparation and irrigation of bypass grafts prior to use in bypass surgery.
Technological characteristics	The VASOSHIELD Pressure Controlling Syringe is identical to the InPress Syringe and features similar fundamental scientific technology as its other predicate devices.
Performance data	The results of testing and data review demonstrate that the VASOSHIELD Pressure Controlling Syringe meets the established acceptance criteria and performs in a manner equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2008

Maquet Cardiovascular, LLC.
c/o Ms. Christina L. Rowe
Principal Regulatory Affairs Associate
170 Baytech Drive
San Jose, CA 95134

Re: K082725
VASOSHIELD Pressure Controlling Syringe
Regulation Number: 21 CFR 878.4200
Regulation Name: Introduction/drainage catheter and accessories
Regulatory Class: Class II (two)
Product Code: GBX
Dated: September 16, 2008
Received: September 25, 2008

Dear Ms. Rowe:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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 STATEMENT

510(k) number (if known)	K082725
Device name	VASOSHIELD Pressure Controlling Syringe
Indications for Use	The device is indicated for controlling pressure during the preparation and irrigation of bypass grafts prior to use in bypass surgery.

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K082725