MAR 0 3 2014

510(K) SUMMARY

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: February 28, 2014

510(k) number: K131659

Applicant Information:
VasoPrep Surgical LLC
55 Madison Avenue, Suite 400
Morristown, NJ 07960

Contact Person
Robert J. Chin Ph.D.
Phone Number: (650) 593-5225

Device Information:

Trade Name:	VasoPrep Vein Preparation Kit
Classification:	878.4200
Classification Name (Code):	Irrigation Catheter (GBX)

Physical Description:
The VasoPrep Vein Preparation Kit is a convenience kit that consists of a pressure relief valve, bulldog clamp, vessel cannula and introducer, stopcock, syringes, extension tube, vein cup and drapes used in the preparation of bypass grafts prior to use in bypass surgery.

Intended Use:
The VasoPrep Vein Preparation Kit is a sterilized convenience kit indicated for controlling pressure during the preparation and irrigation of bypass grafts prior to use in bypass surgery.

Equivalent Device:
The VasoPrep Vein Preparation Kit is substantially equivalent in intended use and/or method of operation to the DMC Saphenous Vein Distension System (K000704) and the Vasoshield Pressure Controlling Syringe (K082725).

Test Results:
Performance
Results of in-vitro testing, including valve cracking pressure and system leakage, demonstrate that the VasoPrep Vein Preparation Kit is safe and effective for its intended use.

Biocompatibility
The materials used in the VasoPrep Vein Preparation Kit meet the requirements of ISO 10993-1 in accordance with FDA Guidance Memo G-95.

Summary:
Based on the intended use, product, performance, sterilization and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices identified.

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

March 3, 2014

VasoPrep Surgical
c/o Dr. Robert Chin
Regulatory Consultant
55 Madison Avenue, Suite 400
Morristown, NJ 07960

Re: K131659
Trade/Device Name: VasoPrep Vein Preparation Kit
Regulation Number: 21 CFR 878.4200
Regulation Name: Introduction/Drainage Catheter and Accessories
Regulatory Class: Class II
Product Code: GBX
Dated: January 17, 2014
Received: January 24, 2014

Dear Dr. Chin:

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 Bram 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): K131659

Device Name: VasoPrep Vein Preparation Kit

Indications for Use:

The VasoPrep Vein Preparation Kit is a sterilized convenience kit indicated for controlling pressure during the preparation and irrigation of bypass grafts prior to use in bypass surgery.

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)