K090759 page 1/2

APR - 1 2009

510(k) Summary

BioDrain STREAMWAY™ Fluid Management System (FMS)

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.
Applicant	BioDrain Medical, Inc.
Submitter	BioDrain Medical, Inc. 2060 Centre Pointe Boulevard, Suite 7 Mendota Heights, MN 55120 Tel: 651-389-4000 Fax: 651-389-4805
Contact Person	Chad A. Ruwe EVP Operations
Date Prepared	March 14, 2009
Device Trade Name	BioDrain STREAMWAY™ Fluid Management System (FMS)
Device Common Name	Powered Suction Pump
Classification Name	Apparatus, Suction, Ward Use, Portable, AC-Powered (21 CFR 878.4780, Product Code JCX
Classification Panel	General & Plastic Surgery
Predicate Devices	ORwell™ Fluid Collection and Disposal System (K080845); Neptune Waste Management System (K012991)
Intended use	The BioDrain STREAMWAY™ Fluid Management System (FMS) is intended to be used in areas such as Operating Rooms, Intensive Care Units, Pathology Suites, Emergency Rooms, Surgical Centers and Doctors' Offices to collect and dispose of fluid waste.
Device Description	The BioDrain STREAMWAY™ FMS system has been designed to safely remove surgical fluid waste during a surgical procedure. The device is wall mounted in the room in which the procedure is being conducted. It is connected to the hospital/clinic vacuum line system, the hospital/clinic drain system, and electrical power. The device removes waste via a disposable suction tube (not provided with system) from the patient and surrounding area, measures the volume of fluid collected, and disposes of the waste into the hospital drainage system. The device has a self cleaning cycle to clean the internal mechanism of the device. The cleaning solution container and the suction tube to the operative field are disposable. The cleaning solution adapter is reusable.

Performance data	Bench testing was performed to support a determination of substantial equivalence and consisted of packaging, electrical safety testing and all testing identified in the FDA's Guidance for Powered Suction Pumps, September 30, 1998 and Premarket Submissions for Software Contained in Medical Devices. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. A risk analysis of the system and its software was performed and testing was conducted to validate the systems overall operations. Biocompatibility testing is not applicable since the proposed device has no direct patient contact.
Summary of Substantial Equivalence	The BioDrain STREAMWAY™ Fluid Management System (FMS) has the following similarities to the predicate devices: • Similar fundamental scientific technology (all predicates) • Similar operating principle (all predicates) • Fluid collection disposables (all predicates) • Vacuum ranges • Suction Mode • Overflow prevention mechanisms • Suction inlet port dimensions • Electrical Compliance Requirements
Conclusion	Based on the similar indications for use, technological characteristics and performance testing, BioDrain Medical, Inc. believes the BioDrain STREAMWAY™ Fluid Management System (FMS) is substantially equivalent to the ORwell™ Fluid Collection and Disposal System (K080845) and the Neptune Waste Management System (K012991).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2009

BioDrain Medical, Inc.
% Regulatory Technology Services LLC
Mr. Mark Job
1394 25th Street Northwest
Buffalo, Minnesota 55313

Re: K090759
Trade/Device Name: BioDrain STREAMWAY™ Fluid Management System (FMS)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: JCX
Dated: March 20, 2009
Received: March 23, 2009

Dear Mr. Job:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090759

Device Name: BioDrain STREAMWAY™ Fluid Management System (FMS)

Indications for Use:

The BioDrain STREAMWAY™ Fluid Management System (FMS) is intended to be used in areas such as Operating Rooms, Intensive Care Units, Pathology Suites, Emergency Rooms, Surgical Centers and Doctors' Offices to collect and dispose of fluid waste.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM 3/31/09

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090759