K092306

JUL - 9 2010

510(k) SUMMARY

Interrad Medical, Inc. SecurAcath Universal

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Interrad Medical
181 Cheshire Lane
Suite 100
Plymouth, MN 55441

Telephone: 763-225-6699

Facsimile: 763-225-6695

Contact Person: Joseph M. Goldberger, President & CEO, Interrad Medical

Date Prepared: July 8, 2010

Name of Device and Name/Address of Sponsor

Device Name: SecurAcath Universal

Sponsor: Interrad Medical
181 Cheshire Lane
Suite 100
Plymouth, MN 55441

Common or Usual Name

Catheter securement device

Classification Name

Accessory to a percutaneous, implanted, long-term intravascular catheter

Predicate Devices

Interrad SecurAcath Catheter (K082047, K083081)

Venetec Statlock (K943147, now 510(k) exempt)

Arrow Staple Anchoring Device, which is provided with the Teleflex / Arrow Central Venous Catheter Kits (believed to be class I, 510(k)-exempt)

Intended Use / Indications for Use

The SecurAcath Universal Device is indicated for short or long term securement of percutaneous indwelling catheters for intravenous use to the access site by means of a subcutaneous anchor.

Technological Characteristics

The SecurAcath Universal is a single use, sterile device for securing indwelling catheters. The device is a stand-alone accessory to percutaneous indwelling catheters and consists of a subcutaneous anchor that is deployed in the subcutaneous space at the catheter access site to reduce catheter migration and pull-out.

Performance Data

The company performed testing to demonstrate that the device meets all product specifications. In all instances, the SecurAcath Universal functioned as intended.

Substantial Equivalence

The SecurAcath Universal is substantially equivalent to the SecurAcath, Statlock, and Arrow Stapling device. The SecurAcath Universal has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the device and its predicate devices raise no new issues of safety or effectiveness as demonstrated by performance testing conducted. Thus, the SecurAcath Universal is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Interrad Medical, Incorporated
Mr. Joseph M. Goldberger
President & Chief Executive Officer
181 Cheshire Lane, Suite 100
Plymouth, Minnesota 55441

JUL - 9 2010

Re: K092306
Trade/Device Name: SecurAcath Universal
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: June 2, 2010
Received: June 2, 2010

Dear Mr. Goldberger:

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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name:

SecurAcath Universal

Indications for Use:

The SecurAcath Universal Device is indicated for short or long term securement of percutaneous indwelling catheters for intravenous use to the access site by means of a subcutaneous anchor.

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)

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092306