JAN - 9 2004

510(k) SUMMARY

Assigned 510(k) # is K032710

Sponsor's Name and Address and Contact Person:

Apogee Medical, Inc.
90 Weathers Street
Youngsville, NC 27596

Contact Person: Diane N. Peper, RA/QA
Telephone: (919) 570-9605
Facsimile: (919) 570-9611
email address: dpeper@apogeemed.com

Date Summary Prepared: August 22, 2003

Device Name and Classification:

Common Name: Urological Catheter
Classification Name: Gastrology and Urology
Product Code: KOD

Manufacturer:

Apogee Medical, Inc.
90 Weathers Street
Youngsville, NC 27596

Name of Predicate Device(s):

Mentor Self-Cath Closed System	K003873
Hollister InCare Pre-Lubricated Intermittent Catheters	K013483

Device Description:

The Apogee Closed System Intermittent Catheterization Kit is a single-use, disposable, pre-lubricated catheter contained in a sterile collection bag. The Closed System Intermittent Catheter is intended to be used to drain urine from the bladder. When it is not practical or feasible for the patient to drain the bladder into a commode or bedpan, the urine may be drained into the collection bag of the Closed System Intermittent Catheterization Kit. The Closed System Intermittent Catheterization Kit is designed with a collection bag and introducer which provide the mechanism for inserting and advancing the catheter to the bladder without direct hand contact to the catheter, thereby, reducing possibility of contamination.

Statement of Intended Use

The Apogee Closed System Intermittent Catheterization Kit is intended to be used to drain urine from the patient's bladder into a collection bag.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2004

Ms. Diane N. Peper
Regulatory Affairs/Quality Assurance Manager
Apogee Medical, Inc.
90 Weathers Street
YOUNGSVILLE NC 27596

Re: K032710
Trade/Device Name: Closed System Intermittent Catheterization Kit
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 KOD
Dated: October 20, 2003
Received: November 7, 2003

Dear Ms. Peper:

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 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032710

Device Name: Closed System Intermittent Catheterization Kit

Indications For Use:

The Apogee Closed System Intermittent Catheterization Kit is intended to be used to drain urine from the patient's bladder into a collection bag.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032710