OCT 2 9 2004

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

The assigned 510(k) number is: K040959

Contact Person: Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
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Santa Barbara, CA 93111

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Date Prepared: April 7, 2004

Device Name and Classification

Proprietary Name:	Mentor Genesis™ Penile Prosthesis
Common Name:	Penile Prosthesis
Classification Name:	Penile Rigidity Implant
Class:	Class II
Product Code:	78FAE
CFR #:	21 CFR §876.3630

Device Description

The Genesis Penile Prosthesis is a flexible silicone elastomer device designed to be implanted into the penis for the management of erectile dysfunction (commonly known as impotence). The Prosthesis (used in pairs) is inserted into the corpora cavernosa. Each Prosthesis consists of a molded silicone elastomer shaft that incorporates a silver wire coil and silver wire core in the flexible center section and a trimmable proximal section. The distal end is shaped to provide an anatomical fit under the glans penis. The silver wire coil and core in the flexible center section enables the Prosthesis to be moved into an erect position for intercourse, and then moved into a lowered position for concealment under clothing. Placed within the corpus cavernosum and crus of the penis, the Prosthesis will fit firmly at the ischial tuberosity. The ends fit the proximal cul-de-sacs of the cavernosa and provide support to the Prosthesis.

All components of the Genesis Penile Prosthesis incorporate a hydrophilic coating on all external surfaces.

Substantial Equivalence Claim

The Mentor Genesis Penile Prosthesis is essentially identical in design and function to Mentor's Acu-Form Penile Prosthesis (510(k) K900371) with the exception that it has been modified to incorporate a hydrophilic coating. This coating was previously submitted and approved by FDA for Mentor's Titan Inflatable Penile Prosthesis under PMA P000006/S1.

Indications for Use

The Prosthesis is designed for the management of impotence stemming from a variety of causes, including epispadias; pelvic fracture; spinal cord injury or disease; prostatectomy; cystectomy; abdominal-perineal resection; multiple sclerosis; diabetes mellitus; alcoholism; arteriosclerosis and hypertensive vascular disease; priapism; and Peyronie's disease. The Prosthesis may also be used in selected patients with psychogenic impotence.

Summary of Testing

Physical and Mechanical testing conducted on the Genesis Penile Prosthesis included Package Integrity, Water Uptake, Lubricity, Coating Coverage, Retention Angle, Column Strength, Device Length, Cyclic Fatigue and Tail Cap Separation Force. The Genesis device met all test specifications.

Biocompatibility testing performed on the Genesis Penile prosthesis included Cytotoxicity, Systemic Toxicity, Intracutaneous Reactivity, Sensitization, Implantation (30-Day and 12-Week), Mouse Lymphoma, and Bacterial Reverse Mutation (AMES). These tests were conducted in accordance with ISO10993-5. The Genesis Penile Prosthesis met all specifications and passed all testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 2004

Ms. Donna A. Crawford
Director, Domestic Regulatory Submissions
Mentor Corporation
201 Mentor Drive
SANTA BARBARA CA 93111

Re: K040959
Trade/Device Name: Mentor Genesis™ Penile Prosthesis
Regulation Number: 21 CFR §876.3630
Regulation Name: Penile rigidity implant
Regulatory Class: II
Product Code: 78 FAE
Dated: October 8, 2004
Received: October 12, 2004

Dear Ms. Crawford:

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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (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): K040959

Device Name: Mentor Genesis™ Penile Prosthesis

Indications for Use:

The Mentor Genesis Penile Prosthesis is designed for the management of impotence stemming from a variety of causes, including epispadias; pelvic fracture; spinal cord injury or disease; prostatectomy; cystectomy; abdominal-perineal resection; multiple sclerosis; diabetes mellitus; alcoholism; arteriosclerosis and hypertensive vascular disease; priapism; and Peyronie's disease. The Prosthesis may also be used in selected patients with psychogenic impotence.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over the Counter Use

(Per CFR 801.109)

(Optimal Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040959