

Revised Appendix C**510(k) Summary
American MedTech
Rejoyn Penile Support System**

OCT 16 1997

I. General Information on Submitter:

Name: American MedTech, Division of Gain, Inc.
Address: 2124 University Avenue
St. Paul, MN 55114
Telephone: (602) 659-2406
Fax: (602) 647-9261
Name of Contact Person: Mr. John C. Field
Date Summary Prepared: September 30, 1997

II. General Information on Device

Name: Rejoyn Penile Support System
Classification Name: External Penile Rigidity Device

III. Predicate Device: Various pre-amendment "penile splints."**IV. Description of the Device:**

The Rejoyn penile support system consists of a semi-rigid split support sleeve molded from medical grade rubber with an attachment strap. The sleeve is placed over the penis with the split side down and the strap is fastened behind the scrotum. The sleeve is approximately 2 1/4" long. The system may also include a lubricated latex cover which may be worn over the sleeve to enhance comfort.

Another version of the Rejoyn system includes a single-use, disposable support sleeve in lieu of the reusable support sleeve. The single-use sleeve is made of the same materials as the reusable sleeve but is removed after use by breaking off one end of the attachment strap at a specified location.

The Rejoyn system will be available in five different package variations: (1) one support sleeve, three covers and one tube of lubricating jelly; (2) one support sleeve and one tube of lubricating jelly; (3) one support sleeve and three covers; (4) three single-use support sleeves, three covers and one tube of lubricating jelly; and (5) three single-use support sleeves and three covers. Replacement covers and lubricating jelly also will be available separately.

V. Intended Use:

The Rejoyn Penile Support System is intended for use by men who have an inability to engage in sexual intercourse due to a flaccid or partially erect penis resulting from impotence.

VI. Technological Characteristics of Device Compared to Predicate Device:

The technological characteristics of the Rejoyn system are very similar to those of the predicate devices: flexible, but firm, medical grade rubber sleeve; reusability; and easy cleanability.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 1997

American MedTech
A Division of Gain, Inc.
c/o Mr. Donald R. Stone
McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006-1108

Re: K971576
Rejoyn Penile Support System
Dated: August 14, 1997
Received: August 15, 1997
Regulatory Class: Unclassified
Product Code: 78 LKY

Dear Mr. Stone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

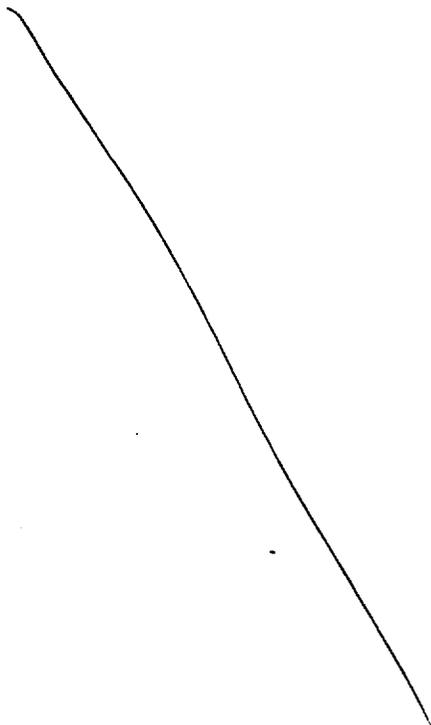
Enclosure

510(k) Number (if known): K971576

Device Name: Rejoyn Penile Support System

Indications For Use:

The Rejoyn Penile Support System is intended for use by men who have an inability to engage in sexual intercourse due to a flaccid or partially erect penis resulting from impotence.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Debra P. Rathbone
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971576

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use