JUL 14 1998

K974040
1 of 2

A. 510(k) Summary

510(K) SUMMARY

SUBMITTER:	Timm Research Company
CONTACT PERSON:	Mr. David Anderson Director of Engineering Timm Research Company 6541 City West Parkway Eden Prairie, MN 55344
DATE PREPARED:	October 23, 1997
TRADE NAME:	C3® External Male Bladder Control Device
CLASSIFICATION NAME and NUMBER: **PRODUCT CODE:**	Urological Clamp for Males Class I, 21 CFR 876.5160 FHA
PREDICATE DEVICE(S):	The C3® External Male Bladder Control Device is identical to Timm Research Company's C3® Male Continence Device, which is a prescription only, urological clamp for males for the management of urinary incontinence (K885323). The OTC C3® Device is identical to Timm Research Company's prescription C3® Device (K885323) in design, function, materials, and intended use. The only difference between the OTC C3® Device and the prescription C3® Device is the labeling. In addition, the OTC C3® Device is substantially equivalent to the penile constriction rings (external penile rigidity devices; product code LKY; unclassified) in the risks from being an OTC device, the design of the labeling, and the general mechanism of action. Therefore, the OTC C3® Device does not raise any new questions of safety and efficacy. An example of an OTC constriction ring is the Revive System manufactured by Revive Systems Corporation (K844445).

DEVICE DESCRIPTION:

The C3® External Male Bladder Control Device is a disposable, externally applied occlusive device intended to manage urinary incontinence in males. The male urethra is occluded by applying an external force on the base of the dorsal side of the penile shaft by means of a clamp.

INTENDED USE:

The C3® External Male Bladder Control Device is intended to be used for the management of urinary incontinence in males.

FUNCTIONAL & SAFETY TESTING:

Because the C3® External Male Bladder Control Device is identical to Timm Research Company's currently marketed prescription C3® Male Continence Device, no functional or safety testing was repeated.

CONCLUSION:

The C3® External Male Bladder Control Device is identical to Timm Research Company's C3® Male Continence Device, which is a prescription only, urological clamp for males for the management of urinary incontinence (K885323). The OTC C3® Device is identical to Timm Research Company's prescription C3® Male Continence Device (K885323) in design, function, materials, and intended use. The only difference between the OTC C3® Device and the prescription C3® Device is the labeling.

In addition, the OTC C3® Device is substantially equivalent to the penile constriction rings (external penile rigidity devices; product code LKY; unclassified) in the risks from being an OTC device, the design of the labeling, and the general mechanism of action. Therefore, the OTC C3® Device does not raise any new questions of safety and efficacy. An example of an OTC constriction ring is the Revive System manufactured by Revive Systems Corporation (K844445).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1998

Mr. Ron Way
Regulatory Affairs
Timm Research Company
6541 City West Parkway
Eden Prairie, MN 55344

Re: K974040
C3 External Male Bladder Control Device - OTC
Dated: May 8, 1998
Received: May 14, 1998
Regulatory Class: I
21 CFR 876.5160/Procode: 78 FHA

Dear Mr. Way:

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 requirements, 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/dsma/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

K974640

510(k) Number (if known):_____

Device Name:_____

Indications For Use:

The C3® External Male Bladder Control Device is intended to be used for the management of urinary incontinence in males.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Rathmell

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974640

Prescription Use____ OR Over–The–Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1–2–96)