

MAY 6 1998

WALLING MEDICAL EQUIPMENT, INC.
3000 Candide Ln., McKinney, Tx 75070
Telephone(972)562-3230 Fax (972)542-0446

K980752

P191

510K SUMMARY

Prepared 3-19-98

Submitted By: Allan Walling

Contact Person: Allan Walling

Device Trade Name: Xtend Ring Kit

Common name: ring kit

Classification name: external penile rigidity device ring

Legally marketed device to which this device is equivalent: Reliant ring

Summary: : The Xtend rings are used by men with erectile dysfunction to improve their ability to have sexual intercourse. When they have a sufficient erection for intercourse a Xtend constriction ring (K980752) is slipped over the base of the penis to act as a partial tourniquet retaining the erection. The ring may be worn for a maximum of thirty minutes before it **MUST be removed. The Xtend ring kit consists of a set of 4 rings. The rings are elastic pharmaceutical quality material which come with an applicator and ring removal hooks. The ring safety removal loops were performance tested for strength. All warnings and precautions from the FDA internet address, www.fda.gov/cdrh/ode/expenrig.html, are included in the premarket notification.**



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 6 1998

Mr. Allan Walling
President
Walling Medical Equipment, Inc.
3000 Candide Lane
McKinney, TX 75070

Re: K980752
Xtend (Over-the-Counter Use)
Dated: March 20, 1998
Received: March 23, 1998
Unclassified/Procode: 78 LKY

Dear Mr. Walling:

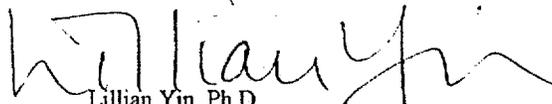
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

Indications for Use

510(k) Number: K980752

Device Name: Xtend

Indications for Use:

The Xtend ring is used to maintain engorgement of the penis for men that are having difficulty with organic or psychological erectile dysfunction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dale R. Halling
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980752

Prescription Use _____
(Per 21 CFR 801.109)

Or

Over-The-Counter ✓