K983438

FEB 8 1999

510(k)SUMMARY

The Max-It device is intended to provide or maintain an erection in men with impotence or premature ejaculation.This is achieved as a result of blood vessel constriction which allows blood to flow into the penis but not to freely flow out (the valvular effect). The external pressure applied by the Max-It device restricts the free flow of blood out of the penis,but not into the penis.

It is equivalent to the venous flow controller in that it constricts the blood flow at the dorsal vein on top of the penis.

It differs from the venous flow controller in that not only does it constrict blood flow at the dorsal vein on top of the penis,the Max-It device also constricts the three cavernous cylinders.These cylinders originate in the anus and transverses the perineum area to the pubis area which forms the base of the penis and extends into and forms the shaft of the penis.Pressure applied to this perineum area and dorsal vein and artery on the dorsal base of the penile shaft at the pubis,will provide the valvular control,which is the formula to natural erection.

FEB 8 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Richard V. Moses, Jr.
Official Correspondent
Dorea Incorporated
1112 N. Madison
Albany, GA 31708-3401

Re: K983438
Max-It™
Dated: December 23, 1998
Received: December 29, 1998
Unclassified/Procode: 78 LKY

Dear Mr. Moses:

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 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). 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,

Capt. Daniel G. Schultz, M.D.
Acting 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): K983438

Device Name: MAX IT

Indications For Use:

"The Max-It device is intended to provide or maintain an erection in men with impotence or premature ejaculation".

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)