

JUN 23 1999

Attachment 3

SUMMARY OF SAFETY AND EFFECTIVENESS
K991814
SPECIAL 510(k) SUMMARY

- 1) **Submitter:** Dexide, Inc.
7509 Flagstone Drive
Fort Worth, TX 76118-6995
Phone No.: (817) 589-1454

Contact Person: John Corzine
Vice President, Research and Development

Date Prepared: May 26, 1999
- 2) **Name of Device:** MultAchoice™ Instruments

Common Name: Laparoscopic Scissors, Graspers, and Dissectors

Classification Name: Laparoscopic, General & Plastic Surgery
- 3) **Predicate Device:** Dexide Inc., Laparoscopic Accessories, K923845
- 4) **Description of Device:** The MultAchoice™ Instruments are a set of reusable and configurable instruments consisting of a Handle, Insulated Shaft, and Instrument Insert that comprise a Laparoscopic Scissor, Grasper, and Dissector.
- 5) **Intended Use:** The MultAchoice™ Instruments may be used in a variety of endoscopic procedures. The MultAchoice™ Scissors are designed for cutting or transecting tissue. The MultAchoice™ Grasper is designed for grasping and manipulating tissue. The MultAchoice™ Dissector is designed for blunt dissection, temporary grasping, and manipulation of tissue.
- 6) The candidate device is identical to the Predicate Device except for the additional capability of being reusable. They have the same intended use and operating principle. They have the same basic design principles and incorporate the same basic materials except for those required to accomplish the reusable specification.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 1999

Mr. John Corzine
Vice President, Research and Development
Dexide, Inc.
7509 Flagstone Drive
Fort Worth, Texas 76118

Re: K991814
Trade Name: MultAchoice™ Instruments
Regulatory Class: II
Product Code: GEI
Dated: May 26, 1999
Received: May 27, 1999

Dear Mr. Corzine:

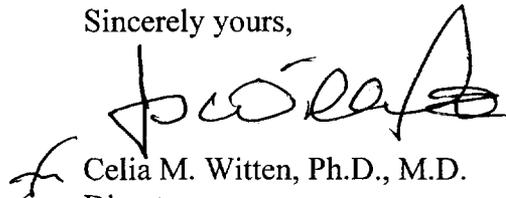
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,

A handwritten signature in black ink, appearing to read "C. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 8

510(k) Number (if known): K 991814

Device Name: MultAchoice™ Instruments

Indications For Use:

MultAchoice Scissor Instrument:

The MultAchoice Scissor may be used in a variety of endoscopic procedures. This device is designed for cutting or transecting tissue. It is fully autoclavable. The insulated shaft of this device has a 5mm OD and a 31cm working length. This shaft may be rotated 360° independent of the instrument handle, thereby permitting increased visibility and access to desired structures. The MultAchoice Scissor has been fitted with a standard banana plug to accept a monopolar connecting cable (not included) for electrosurgery.

MultAchoice Grasper Instrument:

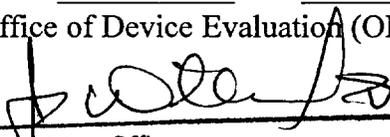
The MultAchoice Grasper may be used in a variety of endoscopic procedures. This device is designed for grasping and manipulating tissue. It is fully autoclavable. The insulated shaft of this device has a 5mm OD and a 31cm working length. This shaft may be rotated 360° independent of the instrument handle, thereby permitting increased visibility and access to desired structures. The MultAchoice Grasper has been fitted with a standard banana plug to accept a monopolar connecting cable (not included) for electrosurgery.

MultAchoice Dissector Instrument:

The MultAchoice Dissector may be used in a variety of endoscopic procedures. This device is designed for blunt dissection, temporary grasping, and manipulation of tissue. It is fully autoclavable. The insulated shaft of this device has a 5mm OD and a 31cm working length. This shaft may be rotated 360° independent of the instrument handle, thereby permitting increased visibility and access to desired structures. The MultAchoice Dissector has been fitted with a standard banana plug to accept a monopolar connecting cable (not included) for electrosurgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991814

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use