3/4/99

Attachment 3

k990379

SUMMARY OF SAFETY AND EFFECTIVENESS

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:	February 1, 1999
2)	Name of Device:	MultAport™ Cannula, Reducer and Accessories
	Common Name:	Cannula, Reducer Seal, and Spike
	Classification Name:	Laparoscopic, General & Plastic Surgery
3)	Predicate Device:	Dexide Inc., MultAport™ Cannula, Reducer and Accessories, K981941
4)	Description of Device:	The "candidate device" is a reusable, stainless steel Cannula and disposable, single-use reduction seal system that threads into the Cannula. The reducer system is composed of silicon rubber, thermoplastic rubber, and plastics. The reusable Sealing Cone and its Seal accommodate the cannula to assist the surgical procedure.
5)	Intended Use:	The Cannulas and accessories are to be used with a Dexide seal package and spike for creating a point of entry for laparoscopic instruments into the abdominal cavity and maintaining pneumoperitoneum.

6) The candidate device has comparable technological characteristics to the predicate device in that it has the same intended use and operating principle. The same basic design principles and incorporates the same basic materials. The same shelf life, similar packaging and the instructions for sterilization are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 1999

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

Re: K990379
Trade Name: MultAport™ Cannula, Reducer and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 1, 1999
Received: February 8, 1999

Dear Mr. Corzine:

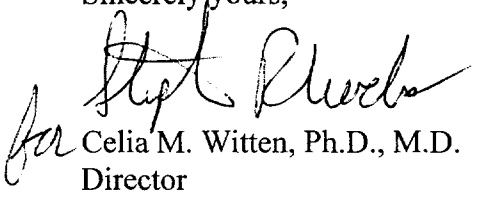
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



for 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 990379

Device Name: MultAport™ Cannula, Reducer and Accessories

Indications For Use:

MultAport Cannulas:

The MultAport reusable cannula is used with an AccuPort Seal or Orbital Reducer Seal and Trocar Spike for creating a point of entry for laparoscopic instruments into the abdominal cavity.

AccuPort 5-12mm Seal:

The AccuPort Seal is a single-use device used during laparoscopy with MultAport Cannulas to maintain pneumoperitoneum while accommodating instruments with diameters ranging from 5mm to 12mm.

Orbital Reducer Seal:

The Orbital Reducer is a single use-device used during laparoscopy with MultAport Cannulas to maintain pneumoperitoneum while accommodating instruments of equal and smaller size.

Blunt Spike:

The reusable Blunt Trocar spike is used with the MultAport Cannulas and AccuPort or Orbital Reducer Seal for creating a point of entry for laparoscopic instruments into the abdominal cavity.

Sealing Cone:

The Sealing Cone is a reusable product designed for use during open laparoscopy procedures. Used in conjunction with the MultAport Cannula and Blunt Spike, the Sealing Cone provides a means to maintain pneumoperitoneum.

Shaft Seal (replacement part for Sealing Cone):

The Sealing Cone is a reusable product designed for used during open laparoscopy procedures. Used in conjunction with the MultAport Cannula and Blunt Spike, the Sealing Cone provides a means to maintain pneumoperitoneum. The shaft seal is designed for use when sealing the cone to the cannula.

(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 K990379

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)