

JUL 29 1998

K 981941

**F: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**510(k) SUMMARY**

- 1) **Submitter:** Dexide, Inc.  
7509 Flagstone Drive  
Fort Worth, TX 76118-6995  
Phone No.: (817) 589-1454  
  
**Contact Person:** Lynette Caldwell  
Director of Quality Assurance  
  
**Date Prepared:** Friday, May 29, 1998
- 2) **Name of Device:** Cannula, Reducer and Accessories.  
  
**Common Name:** Trocar Cannula
- 3) **Predicate Devices:** Dexide, Inc. – K912980  
Aesculap – K942053
- 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.  
  
Accessories:  
Cannulas & Reduction Systems
- 5) **Intended Use:** The Cannulas are to be used with a Dexide seal package and spike for creating a point of entry for laparoscopic instruments into the abdominal cavity.
- 6) **Technological characteristics of this device are comparable to the predicate device in that predicate device(s) is also used to provide a pathway or point of entry for laparoscopic instruments into the abdominal cavity.**

**SECTION G:**

**MANUFACTURER'S STATEMENT OF SUBSTANTIAL EQUIVALENCE**

(To be provided with 510(k) notification for tier II devices)

**STATEMENT OF INDICATIONS FOR USE:** The Cannulas are to be used with a Dexide seal package and spike for creating a point of entry for laparoscopic instruments into the abdominal cavity.

**CLAIMS:** Provides a pathway for entry of laparoscopic instruments of equal size and smaller into the abdominal cavity. The Cannula is reusable and the seal package is single-use disposable. User is responsible for Cannula sterilization. Recommended sterilization methods are listed on the data insert.

This notification contains all of the information required by 21 CFR 807.87.  
A completed copy of the "DRAERD Premarket Notification 510(k) Reviewer's Screening Checklist" is attached.

The candidate device conforms to the following voluntary and mandatory standards:

There are no mandatory existing performance standards that Dexide, Inc is aware.

The candidate device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, and mode of action are equivalent. If the candidate device is a kit, all of the contents of the kit are either pre-Amendment devices or have been cleared for marketing through previous 510(k)'s. The kit contains no drug or biologic products.

The above statements are accurate representations of this 510(k) Premarket Notification and of the device this firm intends to market. All data and information submitted in this Premarket Notification is truthful and accurate and no material fact has been omitted (21 CFR 807.87(J)).

**MANUFACTURER:** Dexide, Inc.

**OFFICIAL CORRESPONDENT:** Lynette Caldwell (signature)  
Lynette Caldwell (printed name)

**TITLE:** Director of Quality Assurance

**DATE:** May 29, 1998



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 29 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Lynette Caldwell  
Director of Quality Assurance  
Dexide, Inc.  
7509 Flagstone Drive  
Fort Worth, Texas 76118

Re: K981941  
Trade Name: Multaport Cannula Reducer and Accessories  
Regulatory Class: II  
Product Code: GCJ  
Dated: May 29, 1998  
Received: June 2, 1998

Dear Ms. Caldwell:

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.

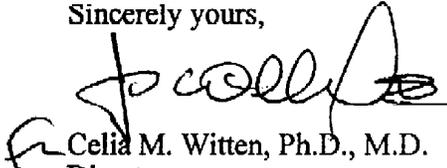
Page 2 - Ms. Lynette Caldwell

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,



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

510(k) Number (if known): K981941

Device Name: 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:**

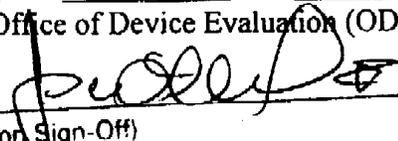
The AccuPort Seal is a single-use device used during laparoscopy with MultAport Cannulas to maintain pneumoperitoneum while accommodating instruments with diameters ranging from 5mm to 12mm.

**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.

(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 12981941

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)