FEB 2 7 2006

510(k) SUMMARY

Granton® Medical Ltd.
121-135°C Self-Seal Sterilization Pouches

1. SUBMITTER NAME AND ADDRESS

Mr. John Bowler
Granton® Medical Limited
Parkway Close
Parkway Industrial Estate
Sheffield S9 4WJ
England

Date Prepared: February 22, 2006

2. DEVICE NAME

Proprietary Name:	Granton® Medical 121-135°C Self-Seal Sterilization Pouches
Common/Usual Name:	Sterilization Pouches
Classification Name:	Sterilization wrap

3. PREDICATE DEVICES

- Self-Seal Sterilization Pouch (K023025)

4. INTENDED USE

The Granton® Medical 121-135°C Self-Seal Sterilization Pouches are intended to be used to enclose another medical device that is to be steam sterilized at 121-135°C by a healthcare provider, following the ANSI/AAMI ST-46 sterilization recommendations. The Self Seal Sterilization Pouches maintain the enclosed device's sterility until used.

5. DEVICE DESCRIPTION

The proposed Granton® Medical 121-135°C Self-Seal Sterilization Pouches (121-135°C Sterilization Pouches) are essentially identical in design and materials to Granton Medical's Self Seal Sterilization Pouch (Self Seal Sterilization Pouch) described in K023025. Like the predicate Self Seal Sterilization Pouch, the 121-135°C Sterilization Pouches are single use bags with an adhesive strip on the open end for sealing the bag prior to sterilization. The six pouch sizes available for the proposed 121-135°C Sterilization Pouches are identical to those of the predicate Self Seal Sterilization Pouch.

The purpose of this submission is to:

- Extend the indications for use to include steam sterilization cycles with temperatures up to 135°C
- Add a throughput process indicator to the paper web of the pouch to distinguish between processed and unprocessed units

6. TECHNOLOGICAL CHARACTERISTICS

The design and materials used for construction of the proposed 121-135°C Sterilization Pouches are identical to those of the parent Self Seal Sterilization Pouch. The proposed 121-135°C Sterilization Pouches are manufactured with a throughput process indicator applied to the paper surface of the pouch using a flexographic printing method. The process indicator ink applied to the proposed 121-135°C Sterilization Pouches is identical in composition to the ink used for the Albert Browne Modified Packaging and Label Steam Indicator (Packaging Steam Indicator) that was the subject of K032801.

7. PERFORMANCE TESTING

Data was provided that demonstrates that the proposed 121-135°C Sterilization Pouches can be used for sterilization of the enclosed medical device in cycles with temperatures up to 135°C. Package integrity testing was also performed to confirm that the seal strength and seal integrity of the proposed 121-135°C Sterilization Pouches are not affected by steam sterilization at 135°C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2006

Granton Medical Limited
C/O Ms. Cynthia J.M. Nolte, Ph.D., RAC
Senior Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K052665
Trade/Device Name: Granton® Medical 121-135°C Self-Seal Sterilization Pouches
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: February 8, 2006
Received: February 10, 2006

Dear Ms. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

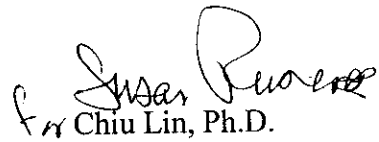
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital ,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K052665

Device Name: Granton® Medical 121-135°C Self-Seal Sterilization Pouches

Indications for Use:

The Granton® Medical 121-135°C Self-Seal Sterilization Pouches (Self Seal Sterilization Pouches) are to be used to enclose another medical device that is to be steam sterilized at 121-135°C by a healthcare provider, following the ANSI/AAMI ST-46 sterilization recommendations. The Self Seal Sterilization Pouches maintain the enclosed device's sterility until used.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

2/27/06

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

K052665