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K020891

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510(k) Summary of Safety and Effectiveness for the Nakao Snare II and Nakao Snare III:

1.) Submitter: Granit Medical Innovations, Inc.
992 Fifth Avenue
New York City, NY 10028

2). Contact Person: Naomi L. Nakao, MD

3.) Summary Preparation Date:
March 15, 2002

4.) Classification Name: Snare, Flexible

5.) Common Name: Monopolar Polypectomy Snare Net Device

6.) Proprietary Name: Nakao Snare II and Nakao Snare III

7.) Substantially Equivalent Device:
K926103 - U. S. Endoscopy Group Inc.

8.) Description of Subject Device:

This disposable product consists of a handle equipped with a male plug for connection to a standard ESU, a flexible sheath and a cable to which a snare loop fitted with a net is attached distally. Upon resection, the device and scope is removed from the patient and the polyp removed from the net together in a continuous retrograde motion. The Snare II version is disposed after one use. The Snare III version may be reused with the same patient. The device is available with different loop sizes and the sheath/cable lengths to accommodate different polyp sizes and endoscope types.

9.) Intended Use:

These devices are intended to endoscopically transect polyps in the gastrointestinal tract (sessile or perdunctuated) using electrocautery. During the same maneuver the polyp is captured, retrieved and submitted for pathological analysis.

10.) Technological Characteristics:

The subject device has the same technological characteristics, is composed of the same type of materials and is of a similar design to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2002

Naomi L. Nakao, M.D.
President
Granit Medical Innovations, Inc.
992 Fifth Avenue
NEW YORK CITY NY 10028

Re: K020891
Trade/Device Name: Nakao Snare II
and Nakao Snare III
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical
unit and accessories
Regulatory Class: II
Product Code: 78 FDI
Dated: March 15, 2002
Received: March 19, 2002

Dear Dr. Nakao

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K020891

Proprietary Name: Nakao Snare II and Nakao Snare III

Common Name: Monopolar Polypectomy Snare Net Device

Indication(s) for Use:

These devices are intended to endoscopically transect polyps in the gastrointestinal tract (sessile or perdunctuated) using electrocautery. During the same maneuver the polyp is captured, retrieved and submitted for pathological analysis.

David G. Lemmon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020891

Prescription Device