DEC 2 7 2002

K023372
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510(k) Summary

10/4/2002

Company:	Onux Medical, Inc 5 Merrill Drive Hampton, NH 03842
Contact Person:	Ruthann R. DePietro, Vice President, Quality Assurance and Regulatory Assurance
Trade or Proprietary Name:	Not available
Common or Usual Name:	Endoscopic stapler and staple
Classification Name:	Endoscopic and/or Accessory, Implantable Staple

Devices to Which Equivalence is Claimed
The subject device has equivalency to the EndoANCHOR produced by Ethicon Endo-Surgery, Inc. (K013749).

Description of Subject Device
The subject device is designed to deliver fixation springs via a minimally invasive sterile disposable instrument that is for single patient use. The fixation springs are made of nitinol and are composed of 3 coils that are approximately .18 inches in diameter. The spring is held within the lumen of a needle. The needle is inserted through the tissue or prosthetic material to be approximated or fixated and the spring is pushed out so that approximately 1 coil of the spring is released. The needle is then withdrawn from the tissue or prosthetic material while the remainder of the spring is pushed out thereby deploying at least one coil on the proximal surface of the tissue or prosthetic material. Because the spring is manufactured such that the coils are naturally pre-compressed against each other, the distal and proximal coils place a compression force on the tissue or prosthetic material that holds them together.

Intended Use of Subject Device
Both the subject device and the EndoANCHOR are indicated for fixation of prosthetic mesh material and approximation of tissue in endoscopic and open surgical procedures.

Comparison of Technical Aspects
The subject device and the EndoANCHOR use an elastic deformation force from nitinol fixation constructs to produce a holding force on the tissue or prosthetic material being approximated or fixated. The subject device uses a spring to compress and hold material that is between its coils while the EndoANCHOR uses opposing pairs of flexible tabs that push against and compress the material held between them.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2002

Ms. Ruthann DePietro
Vice President
Quality Assurance and Regulatory Assurance
Onux Medical, Inc.
5 Merrill Drive
Hampton, New Hampshire 03842

Re: K023372
Trade/Device Name: Coil Fixation Device
Regulation Number: 21 CFR 878.4495; 21 CFR 876.1500
Regulation Name: Stainless Steel Suture; Endoscope and Accessories
Regulatory Class: II
Product Code: NJU; GCJ
Dated: October 4, 2002
Received: October 8, 2002

Dear Ms. DePietro:

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 (301) 594-4659. 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" (21CFR 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,

for Mark N Melkerson

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

Enclosure

510(k) Number (if known): K023372

Device Name: Coil Fixation Device

Indications For Use:

The Coil Fixation Device is intended for fixation of prosthetic material and approximation of tissue in endoscopic and open surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K023372