

JAN 6 2006

510(k) SUMMARY

Roei Medical Technologies Ltd.'s Roei Working Element and Roei Cutting Loops

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: Jonathan S. Kahan

Date Prepared: November 21, 2005

Name of Device and Name/Address of Sponsor

Roei Working Element and Roei Cutting Loops
Roei Medical Technologies, Ltd.
The Herzeliyah Business Park
85 Medinat Hayehudim Street
Tower G, 8th Floor
Israel
Phone: 011-972-9-970-1822
Facsimile: 011-972-9-970-1866

Common or Usual Name

Urological Resectoscope Accessories

Classification Name

Resectoscope, Working Element. Endoscope and Accessories.
Endoscopic electrosurgical unit and accessories.

Predicate Devices

Roei Working Elements and Roei Cutting Loops (K050910)

Intended Use

The Roei Working Element and Roei Cutting Loops are device accessories intended for use with monopolar resectoscope systems for the resection of soft tissue and are indicated for use in transurethral bladder tumor resection (TURBT), transurethral prostatic and bladder biopsy, and transurethral resection of the prostate (TURP).

Technological Characteristics

The Roei Working Element and Cutting Loops use the same fundamental operating characteristics as other resectoscope working elements and electrode cutting loops. The Roei Working Element includes an actuating handle, a tube to accommodate the optics, and a mechanism to which the disposable Roei Cutting Loops are attached. The proximal end of the Roei Working Element has a connection port for connection of a resectoscope optics element. The opposite end of the Roei Working Element has a connection port that accommodates a resectoscope sheath used to encase the tube and the Roei Cutting Loop. Additionally, the Roei Working Element provides an electrical connection box with an inlet receptacle for connection of a resectoscope's electrosurgical cable that is then attached to a monopolar electrosurgical generator. Once the Roei Working Element and Cutting Loop are attached to a resectoscope system, the Roei Cutting Loop receives electrical current from the electrosurgical generator. The electrical current transmitted to the Cutting Loop is then used to resect the targeted soft tissue.

In addition to serving as the housing for the Roei Cutting Loops, optics and electrical connections, the Roei Working Element permits translation of the axial motion of the handgrip into a circular axis movement of the Cutting Loop independent of the resectoscope sheath. This circular axis movement provides the ability for the surgeon to move the Cutting Loop in a side-to-side clockwise or counterclockwise direction through the soft tissue, according to the operating handle position. Furthermore, the Roei Working Element allows for a linear motion of the loop allowing complete retraction of the loop within the sheath during surgical procedures.

Substantial Equivalence

The modified Roei Working Element and Roei Cutting Loops have a similar intended use and indications for use as the previously cleared Roei Working Element and Roei Cutting Loops. In addition, the modified Roei Working Element and Roei Cutting Loops have the same principles of operation as its predicate. The minor technological differences between the modified Roei Working Element and

Roei Cutting Loops and the predicate, namely the longitudinal movement mechanism and adjustment of the distal end of the cutting wire connection, do not raise new questions of safety or efficacy as confirmed by the company's design control system requirements. Furthermore, similar to its predicate, the modified Roei Working Element and Roei Cutting Loops when used as accessories to resectoscopes and monopolar electrosurgical generators will be in compliance with the following recognized consensus standards prior to marketing the device: (1) IEC 6061-2-2, Third Ed. (1998-09): Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment; and (2) AAMI/ANSI HF 18 (2001): Electrosurgical devices. Thus, the modified device is substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Roei Medical Technologies
c/o Mr. Jonathan S. Kahan
Hogan & Hartson L.L.P
Columbia Square
555 Thirteenth Street, N.W.
WASHINGTON DC 20004

Re: K053322

Trade/Device Name: Roei Working Element and Roei Cutting Loops

Regulation Number: 21 CFR §876.4300

Regulation Name: Endoscopic electrosurgical unit and accessories

Regulatory Class: Class II

Product Code: FAS

Dated: December 19, 2005

Received: December 19, 2005

Dear Mr. Kahan:

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

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



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

Enclosure

Indications for Use Statement

510(k) Number (if known): K053322

Device Name: Rои Working Element and Rои Cutting Loops

Indications for Use:

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Prescription Use X
(Per 21 C.F.R. 801.109)

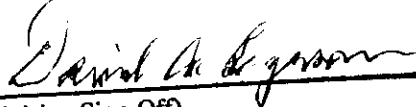
OR

Over-The-Counter Use

(Optional Format 1-2-96)

(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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053322