Attachment 2
Revised - October 5, 2009

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510(k) Summary

Owner's Information: Kenna S. Given, M.D.
748 Tripps Court
Augusta, GA 30909
Tel: (706) 721-6945 Fax: (706) 721-6931

OCT 2 8 2009

Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc.

510(k) Number: K082584

Trade/Proprietary Name: Given Electrosurgical Needle

Common Name: Electrosurgical Instrument

Classification Name: Electrosurgical Cutting & Coagulation Device and Accessories (21 CFR 878.4400)

Product Code: GEI

Legally Marketed Predicate Devices: Stryker Leibinger Colorado MicroDissection Needle®
510(k) #s: K033232; K000348; K881763

Device Description:

The Given Electrosurgical Needle is a single patient use needle electrode for use in monopolar electrosurgical handpieces. The skin which is usually anesthetized with a topical and/or injectable anesthetic. The monopolar generator is set at the cutting mode to 1.5 to 1.75 Watts. The needle is introduced into the vein located within the skin. The current is then applied with destruction of the vein while the insulation protects the surrounding tissue. The needle is withdrawn and additional veins are then treated in a similar fashion. The needle is made of Tungsten Carbide and the insulation is Parylene-C which are both biocompatible materials that have been used extensively in electrosurgical electrodes.

Intended Use:

The Given Electrosurgical Needle is used to apply electrosurgical current directly into a spider vein located within the skin. The electrosurgical current destroys the spider vein.

Similarities and Differences of the Proposed Devices to the Predicate Devices:

Similarities
The Given Electrosurgical Needle has the same basic technology characteristics for an electrosurgical electrode for use in monopolar electrosurgical handpieces. It is intended for precision cutting and cauterizing of soft tissue as the predicate devices, and the indications for use are the same except for the specific additions as noted below.

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Differences
The Given Electrosurgical Needle utilizes some of the exact materials as the predicate devices; however, all materials are known biocompatible materials that have been used in electrosurgical electrodes or electrosurgical instruments.

Conclusion:

The Given Electrosurgical Needle has the same principles of operation, and technological characteristics as the predicate device. The Given Electrosurgical Needle has determined a specific intended use from results of testing as presented in the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 2 8 2009

Tripps Court Enterprises, Inc.
% Regulatory Resources Group, Inc.
Ms. Julie Stephens
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K082584
Trade/Device Name: Given Electrosurgical Needle
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 5, 2009
Received: October 6, 2009

Dear Ms. Stephens:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082584

Device Name: Given Electrosurgical Needle

Indications For Use:

The Given Electrosurgical Needle is used to apply electrosurgical current directly into a spider vein located within the skin. The electrosurgical current destroys the spider vein.

Prescription Use ___X____ 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 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082584