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510(k) Summary of Safety and Effectiveness

1. Submitter's Name
Relievant MedSystems, Inc.
2688 Middlefield Rd, Suite A
Redwood City, CA 94063

MAR 3 0 2010

2. Company Contact
Adam Savakus
Executive Vice President
Telephone: 650 368-1000
Fax: 650 298-9205

3. Device Name

Trade Name:	INTRACEPT Flexible Bi-Polar RF Probe and Easy Access Instrument Set
Common Name:	Radiofrequency Probe
Classification Name:	Electrosurgical, cutting & coagulation & accessories

4. Date Summary Prepared
March 3, 2010

5. Predicate Device
Relievant MedSystems INTRACEPT Flexible Bi-Polar RF Probe and Curved Instrument Set

6. Description of Device
The Relievant INTRACEPT Flexible Bi-Polar RF Probe and Easy Access Instrument Set are used in conjunction with the Stockert NEURO N50 RF Generator and Interconnect Cable to create radiofrequency lesions in soft tissue. The device is a modification to the Relievant MedSystems INTRACEPT Flexible Bi-Polar RF Probe and Curved Instrument Set incorporating upgraded access and deployment instrumentation. The system delivers temperature-controlled, radiofrequency (RF) energy into targeted tissue via the probe to create lesions in soft tissue. The Instrument Sets are used to provide access to the target tissue.

7. Intended Use
The INTRACEPT Flexible Bi-Polar RF Probe and Easy Access Instrument Set are intended to be used with radiofrequency (RF) generators for the thermal coagulation of soft tissues.

8. Comparison of Technological Characteristics
The INTRACEPT Flexible Bi-Polar RF Probe and Easy Access Instrument Set are substantially equivalent in design, materials, function and intended use to the following device cleared for commercial distribution:
Relievant MedSystems INTRACEPT Flexible Bi-Polar RF Probe and Curved Instrument Set

9. Summary of Performance Data
The INTRACEPT Flexible Bi-Polar RF Probe and Easy Access Instrument Set were tested and compared to the predicate device. Ex vivo and in vitro data demonstrated that the INTRACEPT Easy Access Instrument Set achieves RF Probe placements with less procedural complexity and improved ergonomics, which may result in reduced overall procedure time and more efficient instrument exchange. The test data gathered demonstrate that this device is substantially equivalent to the predicate device. No new safety or effectiveness issues have been raised.

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

Relievant Medsystems, Inc.
% Mr. Adam Savakus
Executive Vice President
2688 Middlefield Road, Suite A
Redwood City, California 94063

MAR 3 0 2010

Re: K100641
Trade/Device Name: INTRACEPT Flexible RF Probe and Easy Access Instrument Set
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 04, 2010
Received: March 05, 2010

Dear Mr. Savakus:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

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 Statement

510(k) Number (if known): K100641

Device Name: INTRACEPT Flexible Bi-Polar RF Probe and Easy Access Instrument Set

Indications for Use:

The INTRACEPT Flexible Bi-Polar RF Probe and Easy Access Instrument Set is intended to be used in conjunction with radiofrequency (RF) generators for the thermal coagulation of soft tissues.

Prescription Use _X_ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

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

_____ _____ _____ _____
_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100641