K083856

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510(k) Summary of Safety and Effectiveness

JAN 22 2009

1 Submitter's Name

Relievant MedSystems, Inc
713 Sandoval Way
Hayward, CA 94544

2 Company Contact

Mark Smutka
Regulatory, Clinical, and Quality Consultant
Telephone – 510-489-1080
Fax – 510-489-1082

3 Device Name

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

4 Date Summary Prepared

December 19, 2008

5 Predicate Device

Relievant MedSystems INTRACEPT Bi-Polar RF Probe and Instrument Set (K070443)

6 Description of Device

The Relievant INTRACEPT Flexible Bi-Polar RF Probe and Curved Instrument Sets 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 Bi-Polar RF Probe and Instrument Set to incorporate a curved instrument set and a more flexible tip of the radiofrequency probe 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 Curved Instrument Set is 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 Curved Instrument Set are substantially equivalent in design, materials, function and intended use to the following device cleared for commercial distribution
Relievant MedSystems INTRACEPT Bi-Polar RF Probe and Instrument Set (K070443)

9 Summary of Performance Data

The INTRACEPT Flexible Bi-Polar RF Probe and Curved Instrument Set was tested and compared to the predicate device In vivo data demonstrated that the INTRACEPT Flexible Bi-Polar RF Probe and Curved Instrument Set creates clinically relevant lesions that are equivalent in size to the predicate device 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
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2009

Relievant MedSystems, Inc
% Mr Mark Smutka
Regulatory, Clinical and Quality
Consultant
713 Sandoval Way
Hayward, California 94544

Re K083856
Trade/Device Name INTRACEPT Flexible Bi-Polar RF Probe and Curved Instrument Set
Regulation Number 21 CFR 878 4400
Regulation Name Electrosurgical cutting and coagulation device and accessories
Regulatory Class II
Product Code GEI
Dated December 23, 2008
Received December 24, 2008

Dear Mr Smutka

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 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 (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson

Mark N Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K083856

Device Name INTRACEPT Flexible Bi-Polar RF Probe and Curved Instrument Set

Indications for Use

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

Prescription Use X (Per 21 C F R 801 109) AND/OR Over-The-Counter Use____ (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)

David Krome for MKM 1/22/2009

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

510(k) Number K083856