K070443

OCT 5 2007

## 510(k) Summary of Safety and Effectiveness



1. Submitter's Name
Relievant MedSystems, Inc.
713 Sandoval Way
Hayward, CA 94544

2. Company Contact
Mark Smutka
Regulatory and Clinical Consultant
Telephone – 510-489-1080
Fax – 510-489-1082

3. Device Name

| | |
|---|---|
| Trade Name: | INTRACEPT Bi-Polar RF Probe and Instrument Set |
| Common Name: | Radiofrequency Probe |
| Classification Name: | Radiofrequency Lesion Probe |

4. Date Summary Prepared
September 27, 2007

5. Predicate Devices
-Neurotherm Disposable Radiofrequency Cannula (K994344)
-InCircle Bi-Polar RF Ablation Device (K070711)
-Stryker RF Coaxial Bipolar Electrodes and Cannulae (K043442)

6. Description of Device
The Relievant INTRACEPT Bi-Polar RF Probe and Instrument Sets are used in conjunction with the Stockert NEURO N50 RF Generator and Interconnect Cable to create radiofrequency lesions in soft tissue. 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 and are available in a Standard Length and an Extra Length version.

7. Intended Use
The INTRACEPT Bi-Polar RF Probe and 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 Bi-Polar RF Probe and Instrument Set are substantially equivalent in design, materials, function and intended use to the following devices cleared for commercial distribution:

K070443

-Neurotherm Disposable Radiofrequency Cannula (K994344)
-InCircle Bi-Polar RF Ablation Device (K070711)
-Stryker RF Coaxial Bipolar Electrodes and Cannulae (K043442)



9. Summary of Performance Data

The INTRACEPT Bi-Polar RF Probe and Instrument Set was tested and compared to predicate devices. In vivo data demonstrated that the INTRACEPT Bi-Polar RF Probe and 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 devices. 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

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

OCT 5 2007

Re: K070443
Trade/Device Name: INTRACEPT Bi-Polar RF Probe and Instrument Set
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 27, 2007
Received: September 28, 2007

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND/GSDB
D.O.
f/t:GJM:kxl:10-04-07

OC Numbers:

| | |
|---|---|
| **Division of Enforcement A** | 240-276-0115 |
| Dental, ENT and Ophthalmic Devices Branch | 240-276-0115 |
| OB/GYN, Gastro. & Urology Devices Branch | 240-276-0115 |
| General Hospital Devices Branch | 240-276-0115 |
| General Surgery Devices Branch | 240-276-0115 |
| **Division of Enforcement B** | 240-276-0120 |
| Cardiovascular & Neurological Devices Branch | 240-276-0120 |
| Orthopedic, Physical Medicine & Anesthesiology Devices Br | 240-276-0120 |

# Indications for Use

510(k) Number (if known): K070443
K070443

Device Name:
INTRACEPT™ Bi-Polar RF Probe and Instrument Set

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

Prescription Use __X__ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K070443

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

**510(k) Number** K070443