K102461

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Invasix Ltd.

Fractora

JUN - 2 2011

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter's information

Name:	Invasix Ltd.
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Contact:	Dr. Amir Waldman VP Regulatory Affairs

Device information

Trade/Proprietary name:	Fractora
Classification name:	Device, Electrosurgical Cutting and Coagulation and Accessories (21CFR §878.4400)
Product code:	GEI

Predicate device

Matrix RF applicator (K073572).

Intended use:

The Fractora is intended for dermatological procedures requiring ablation and resurfacing of the skin.

Device Description:

The Fractora is composed of a console, hand held applicator, and disposable tip, designed to deliver bipolar radiofrequency electrical current to the skin surface, via an array of multi-electrode pins.

Performance data:

In this submission bench testing performance data as well as histology data presented.

Substantial Equivalence:

Intended use equivalence

Fractora's intended use is identical to the intended use of the predicate device: Matrix RF applicator.

Technological equivalence

The Fractora hand piece is designed to deliver radiofrequency energy to the skin in a non-homogeneous fractional manner, via an array of multi-electrode pins. The array delivers bipolar RF energy to the skin, resulting in heating of skin directly below the electrodes, to temperatures leading to ablation and resurfacing of the skin. The predicate device uses similar technological characteristics.

The main output parameter that determines the ablative and coagulative effects is energy per pin, which is identical for Fractora and the predicate device. Minor differences in the number of pins, and array dimensions, may slightly affect the number of pulses required to cover the treatment area.

The Fractora is substantially equivalent to its predicate device. The data in this 510(k) submission demonstrate that the Fractora device has similar output and intended use as other predicate device. Therefore is substantially equivalent to its predicate devices.

Based upon an analysis of the overall performance characteristic for the device, Invasix Ltd. believes that no significant differences exist between the Fractora and the predicate device. Therefore the Fractora should raise no new issues of safety or effectiveness.

March 25, 2011

Date

Dr. Amir Waldman,
VP Regulatory Affairs
Invasix Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUN - 2 2011

Re: K102461
Trade/Device Name: Fractora
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 26, 2011
Received: May 27, 2011

Dear Dr. Waldman:

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/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

510(k) Number (if known) K102461

Device Name Fractora

Indications For Use:

Fractora is intended for dermatological procedures requiring ablation and resurfacing of the skin.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K102461