## 3. 510(K) SUMMARY

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 878.4400.

Date Prepared: 07/19/10

510(k) number: K091310

AUG 1 1 2010

**Applicant Information:**
DFine Inc.
3047 Orchard Parkway
San Jose, CA 95134, USA

**Contact Person:**
Sandeep Saboo
Vice-President, Quality Assurance and Regulatory Affairs
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**Device Information:**

| | |
|---|---|
| Trade Name: | Ablation Generator System, and Ablation Instrument |
| Classification: | Class II (for both, Ablation Generator System and Ablation Instrument) |
| Classification Name: | Electrosurgical Cutting and Coagulation and Accessories |
| Product Code: | GEI |
| Regulation No.: | 21CFR ~~888.4400~~ 878.4400 |

**Physical Description:**
Ablation Generator System is a microprocessor controlled radiofrequency (RF) generator designed for use with the hand held, bipolar, sterile, single use Ablation Instrument for percutaneous delivery of low power bi-polar RF energy by the physician to the tissue site in contact with the Electrode of the Ablation Instrument.

The Ablation Instrument is a hand held, bi-polar, sterile, single use device designed specifically for use with the Ablation Generator System. The user connects the Ablation Instrument to the Ablation Generator System using the AE Cable (for delivery of RF energy). The user positions the distal tip of the device containing the active and return electrodes at the tissue site where the specific treatment is to be performed.

**Indications For Use:**
The Ablation Generator System and Ablation Instrument are indicated for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.

**Test Results:**

*Performance*

Results of in-vitro and in-vivo testing (performance, mechanical, electrical, software) demonstrate that the Ablation Generator System and the Ablation Instrument function as intended and the results of tests were as expected.

*Biocompatibility*

The materials used in the Ablation Generator System and Ablation Instrument meet the requirements of ISO 10993-1.

**Substantial Equivalence and Summary:**

The subject device:

- Ablation Instrument has the same technological characteristics and principles of operation as its predicate, ArthroCare Cavity SpineWand [K063172, manufactured by ArthroCare Corporation]. The intended use and indications for the Ablation Instrument is a subset of that for its predicate device.
- Ablation Generator System (used only with the Ablation Instrument) has the same technological characteristics and principles of operation as its predicate, ArthroCare Orthopedic Electrosurgery System [K992581] when used with ArthroCare Cavity SpineWand [K063172, manufactured by ArthroCare Corporation]. The intended use and indications for the Ablation Generator is a subset of that for its predicate device.

The minor technological differences between the subject devices (Ablation Generator System and Ablation Instrument) and their predicate devices (ArthroCare Orthopedic Electrosurgery System and ArthroCare Cavity SpineWand) raise no new issues of safety or effectiveness. Performance data demonstrate that Ablation Generator System and the Ablation Instrument are as safe and effective as the predicate devices for their intended use. Thus, the Ablation Generator System and Ablation Instrument are substantially equivalent to their identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DFine, Inc.
% Mr. Sandeep Saboo
Vice President, Quality Assurance
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3047 Orchard Parkway
San Jose, California 95134

AUG 1 1 2010

Re: K091310
Trade/Device Name: Ablation Instrument and Ablation Generator System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 19, 2010
Received: July 20, 2010

Dear Mr. Saboo:

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,

for Dep Dir

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

Enclosure

K091310

## 2. INDICATIONS FOR USE STATEMENT

AUG 11 2010

510(k) Number (if known): K091310

Device Name: Ablation Instrument and Ablation Generator System

Indications for Use:

**Ablation Instrument:**
The Ablation Instrument is indicated for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.

**Ablation Generator System:**
The Ablation Generator is indicated for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K091310