K082786 DEC 03 2008

# 510(k) Summary for the PEAK Surgery System



1. **Submitter name and address:**

PEAK Surgical, Inc.
2464 Embarcadero Way
Palo Alto, CA 94303
Phone: 650-331-3020
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Contact: Grace Carlson, MD

Date Prepared: September 22, 2008

2. **Device Name:**

| | |
|---|---|
| Trade Name: | PEAK Surgery System, consisting of:<br>PULSAR™ Generator and<br>PEAK PlasmaBlade™ Tissue Dissection Devices |
| Common Name: | Electrosurgical Device and Accessories |
| Classification Name: | Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400) |

3. **Predicate Devices:**

PULSAR Generator and PEAK PlasmaBlade Tissue Dissection Device (K073057)
Ellman Surgi-Max Generator (K061174)
ELECTROMEDICS FAS-CLEAN electrode (K073616)

4. **Device description:**

The PEAK Surgery System consists of the PULSAR Generator, PEAK PlasmaBlade Tissue Dissection Devices, and an optional wireless foot pedal. The PULSAR Generator is a microcontroller based, isolated output, electrosurgical unit that has been designed to produce monopolar and bipolar RF energy for cutting and coagulation during surgery. The PULSAR Generator is used with the PEAK PlasmaBlade Tissue Dissection Devices, which are single use, sterile handpieces for monopolar energy delivery. The PEAK PlasmaBlade Tissue Dissection Devices consists of an insulated blade electrode, rotating bendable shaft, handle with integrated controls, and a cable. An optional footswitch may be used to operate the system in lieu of the controls on the PlasmaBlade handpieces.

K082786

Page 2 of (2)

**5. Intended Use:**

The PEAK Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.

**6. Technological Characteristics:**

The PEAK Surgery System is similar to the predicate devices in that they are all electrosurgical instruments used to cut tissue and coagulate soft tissue, utilizing RF powered distal ends.

**7. Performance Data:**

Preclinical laboratory and performance tests were executed to ensure the devices functioned as intended and met design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate devices, and meets safety and effectiveness criteria.

**8. Sterilization:**

The PEAK PlasmaBlade Tissue Dissection Devices are provided sterile. The device is not intended for reuse or resterilization.

**9. Conclusions:**

By virtue of design, materials, function, and intended use, the PEAK Surgery System is substantially equivalent to FDA-cleared devices currently marketed in the United States. In establishing substantial equivalence to the predicate devices, PEAK Surgical evaluated the indications for use, materials incorporated, product specification and energy requirements of those systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 03 2008

Peak Surgical, Inc.
% Grace A. Carlson, MD
Consultant, Regulatory and Clinical Affairs
2464 Embarcadero Way
Palo Alto, California 94303

Re: K082786
Trade/Device Name: PEAK Surgery System (PULSAR™ Generator and PEAK PlasmaBlade™ Tissue Dissection Devices
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 22, 2008
Received: September 23, 2008

Dear Dr. Carlson:

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

Enclosure

## Indications for Use

510(k) Number (if known): K082786

Device Name: PEAK Surgery System (PULSAR™ Generator and PEAK PlasmaBlade™ Tissue Dissection Devices

Indications for Use:

The PEAK Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.

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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. O'Hara for mxm

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

**510(k) Number** K082786