K070353

3 510k Summary

3.1 Company

MAY - 2 2007

Kelsey, Inc.
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Chicago, IL 60603

3.2 Contact

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Regulatory Consultant to Kelsey
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Catonsville, MD 21228
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3.3 Date Prepared

January 24, 2007

3.4 Device Name

Trade Name:	Kelsey Interstitial Laser Therapy System
Classification Name:	Laser powered surgical instrument

3.5 Predicate Devices

Diomed 15 Plus.....K012398
Indigo 830.....K954195
Indigo Diffuser Tip Fiberoptic w/Temp Sensing Option.....K003953
Cryocare™ Surgical System.....K003811

3.6 Device Description

The Kelsey Interstitial Laser Therapy system consists of the following:

- One laser probe, a 14 gauge needle, 304 stainless steel with one (1) thermistor attached.
- One temperature probe, a 14 gauge needle, 304 stainless steel with five (5) thermistors attached.
- Thermistor temperature to digital converter.
- Syringe infusion pump capable of accurately infusing a normal saline solution at variable flow rates to 1 cc per minute, continuously adjustable, including bolus function.
- Laser diode source, 1-8 watts, 805 nominal nanometer wavelength.
- Storage cart.

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- Personal computer running Windows XP with Service Pack 2, or better, including monitor and keyboard.

3.7 Intended Use

The intended use for the Kelsey Interstitial Laser Therapy System is the same as the predicate devices. Its intended use is as a surgical instrument in the excision of external tumors and lesions, complete and partial resection of internal organs, treatment of tumors and lesions, skin incision and tissue dissection and ablation.

3.8 Indications for Use

The Kelsey Interstitial Laser Therapy System is indicated for the treatment of fibroadenomas of the breast, with tumor sizes up to 20 mm; and for general surgery procedures including incision, excision and ablation of soft tissues; and coagulative necrosis and interstitial laser coagulation of soft tissue.

3.9 Comparison of Technological Characteristics

The Kelsey Interstitial Laser Therapy System is a self-contained surgical laser that generates near-infrared laser radiation. A fiber optic delivery system is coupled to the laser to deliver laser radiation to the target tissue. These technologic characteristics are shared with the previously identified predicate devices.

3.10 Performance Data

Bench and clinical testing demonstrated that the use of the Kelsey ILT device for the ablation of breast fibroadenoma tissue is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kelsey, Inc.
% Mr. Paul Ketteridge
Regulatory Consultant
303 Patleigh Road
Catonsville, Maryland 21228

MAY - 2 2007

Re: K070353
Trade/Device Name: Kelsey Interstitial Laser Therapy System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 31, 2007
Received: February 6, 2007

Dear Mr. Ketteridge:

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

2 Indications for Use

510(k) Number (if known): K070353

Device Name: Kelsey Interstitial Laser Therapy System

Indications for Use:

The Kelsey Interstitial Laser Therapy System is indicated for the treatment of fibroadenomas of the breast, with tumor sizes up to 20 mm; and for general surgery procedures including incision, excision and ablation of soft tissues; and coagulative necrosis and interstitial laser coagulation of soft tissue.

Prescription Use (21 CFR 801 Subpart D)	☒	And/Or	Over-The-Counter Use (21 CFR 807 Subpart C)	☐

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070353