K071814

OCT 16 2007

5.0 510(k) Summary or 510(k) Statement

510(k) Summary

1.	**510(k) owner's name:**	Minrad, Inc.
2.	**Address:**	50 Cobham Drive Orchard Park, NY 14127 Phone: (716) 855-1068 Facsimile: (716) 855-1078
	Contact:	John McNeirney, Senior Vice President & Chief Technical Officer
3.	**Preparation Date:**	June 29, 2007
4.	**Device name:**	Light Sabre™ Spinal Access Device
5.	**Common name:**	Biopsy Needle
6.	**Product classification:**	Instrument, Biopsy (21 CFR 876.1075, Product Code KNW)
7.	**Predicate device:**	Light Sabre™ Bone Biopsy Needle (K982735)
8.	**Description of device:**	The Light Sabre™ Spinal Access Device is a single-use disposable device that is used to obtain biopsies of bone and/or bone marrow and is used to provide a port of entry to place guidewires during percutaneous spinal procedures. The device will consist of a stainless steel stylet with an attached plastic hub that will fit into a stainless steel cannula that has an attached plastic hub. A removable handle will also be provided with the device. The Light Sabre™ Spinal Access Device is designed to work with the MINRAD SabreSource™ Targeting System, as accepted for market

		under K022935. To do this, the Light Sabre™ Spinal Access Device incorporates a collimating channel and light-dispersing element directly into the stylet assembly. When the Light Sabre™ Spinal Access Device is aligned with the laser beam of the SabreSource™ Targeting System, the laser will clearly illuminate the light-dispersing element. Whenever the device is moved out of the path, as defined by the laser beam, the light-dispersing element of the Light Sabre™ Spinal Access Device ceases to glow.
9.	**Voluntary standards:**	There are not any specific standards promulgated but the Light Sabre™ Spinal Access Device will be manufactured in accordance with following standards: 1. ASTM F1140-00 2. ANSI/AAMI/ISO 11137:1994 3. ANSI/AAMI/ISO 11737-1:1995 4. AAMI TIR 17:1997 5. AAMI TIR 27:2001 6. ANSI/AAMI/ISO TIR 15843:2000 7. ANSI/AAMI ST 72:2002 8. ASTM D-5276-98(2004) 9. ASTM F88-06 10. ISO 11607 11. ISO 9626:1991 12. ISO 594:1986 13. ISO 10993-1:2003 14. ISO 10993-5:1999 15. ISO 10993-10:2002
10.	**Intended use and indication for use:**	The Light Sabre™ Spinal Access Device is a single-use disposable device that is used to obtain biopsies of bone and/or bone marrow and is used to provide a port of entry to place guidewires during percutaneous spinal procedures.
11.	**Technological characteristics:**	**Indications for Use:** A single-use disposable device that is used to obtain biopsies of bone and/or bone marrow and is used to provide a port of entry to place guidewires during percutaneous spinal procedures. **Sterility:** Provided sterile for single use **Needle Type:** Cannula – Stainless Steel with Plastic Hub Assembly; Stylet – Stainless Steel with Plastic Hub Assembly

Needle Length: 10 - 15cm
Needle Gauge/Diameter: 8, 11, 13 Gauge
Stainless Steel Material: Stainless Steel 304
Stylet/Cannula Hub Material: Gamma Stable Polycarbonate
Method of Sterilization: Gamma Radiation
Includes method to remove biopsy sample: Included in Packaging is Core Sampler made of Stainless Steel 304
Able to connect Syringe for Aspiration or Injection: Luer Lock per ISO 594-2:1998 (E) on Luer Adapter Component

12. Testing

All materials used in the fabrication of the Light Sabre™ Spinal Access Device will be evaluated through biological qualification safety tests as outlined in the applicable sections of ISO 10993. These materials will also be tested in accordance with industry recognized test methods that are applicable based on the intended use of the device.

This concludes the 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2007

Minrad, Inc.
% Mr. John McNeirney
Senior VP and Chief Technical
Officer
50 Cobham Drive
Orchard Park, New York 14127

Re: K071814
Trade/Device Name: Light Sabre™ Spinal Access Device
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: August 30, 2007
Received: September 7, 2007

Dear Mr. McNeirney:

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

4.0 Indications for Use Statement

510(k) Number (if known): K071814

Device Name: Light Sabre™ Spinal Access Device

Indications for Use:

The Light Sabre™ Spinal Access Device is a single-use disposable device that is used to obtain biopsies of bone and/or bone marrow and is used to provide a port of entry to place guidewires during percutaneous spinal 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Division of General, Restorative, and Neurological Devices

510(k) Number K071814