K013040

# EXHIBIT A – 510(K) SUMMARY
# MINRAD, INC. LIGHT SABER™ INTRODUCER NEEDLE

DEC 0 7 2001

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

MINRAD, INC.
847 Main Street
Buffalo, NY 14203

Phone: (716)-855-1068
Facsimile: (716)-855-1071

Contact Person: John Riggi
Director, Regulatory Affairs
Date Prepared: August 29, 2001

**Name of Device and Name/Address of Sponsor**

Light Saber™ Introducer Needle

MINRAD, INC.
847 Main Street
Buffalo, NY 14203

**Common or Usual Name**

Surgical Guide Needle/General and Plastic Surgery, Cannula

**Classification Name**

Surgical Guide Needle/General and Plastic Surgery, Cannula

**Predicate Devices**

1. Introducer Needle Accessory, Oratec Interventions, Inc.
2. Light Saber™ Aspiration Needle, MINRAD, Inc.

# EXHIBIT A – 510(K) SUMMARY
# MINRAD, INC. LIGHT SABER™ INTRODUCER NEEDLE (cont.)

## Intended Use

The Light Saber™ Introducer Needle is intended to be a single use disposable introducer needle/cannula intended for precise placement of guidewires in non-vascular procedures. The Light Saber™ Introducer Needle is generally indicated to gain percutaneous access to the body for surgical procedures and specifically indicated for use with the DRTS to improve the accuracy of needle placement.

## Technological Characteristics

The light Saber Introducer Needle consists of a needle, a collimator, to which a stylet is attached. The stylet is enclosed in a cannula/hub assembly with a matching tip. The female Luer of the cannula hub, for attachment to the syringe, is designed to comply with ISO-594 for "Conical fittings with a 6% (Luer) taper for syringes, needles and other medical equipment." The Light Saber™ Introducer Needles are provided in gauges of 17, 18, and 19 and in lengths of 2¾, 4 and 6 inches. The tip design for these needles will provide either a Trocar or Tuohy point. Depth markings are standard on the cannula at 1cm intervals.

## Substantial Equivalence

The MINRAD, INC. Light Saber™ Introducer Needle is substantially equivalent to the other currently marketed devices, which are referenced above. Except for minor differences in general indications for use, size of the needle and needle tip configurations, the MINRAD, INC. Light Saber™ Introducer Needle is identical to a combination of its predicate devices. These minor differences raise no new issues of safety or effectiveness. Thus, the MINRAD, INC. Light Saber™ Introducer Needle is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Riggi
Director, Regulatory Affairs
MINRAD, Inc.
847 Main Street
Buffalo, New York 14203

DEC 0 7 2001

Re: K013040
Trade/Device Name: Light Saber™ Introducer Needle
Regulation Number: 880.5860, 878.4800
Regulation Name: Piston syringe
Manual surgical instrument for general use
Regulatory Class: II
Product Code: FMF, MDM
Dated: September 7, 2001
Received: September 10, 2001

Dear Mr. Riggi:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# SECTION 5 – INDICATIONS FOR USE

## Indications for Use Form

**510(k) Number (if known):** K013040

**Device Name:** Light Saber™ Introducer Needle

**Intended Use:** A single use disposable introducer needle/cannula intended for precise placement of guide wires in non-vascular procedures.

**Indications for Use:** For use with the Dual Radiation Targeting System (ie: DRTS) to improve the accuracy of the needle placement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhauser

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

510(k) Number K013040

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)