K041846

AUG 2 6 2004

510(k) SUMMARY
MINRAD INC.
SabreSource™ Drape

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

Contact Person
John McNeirney
MINRAD INC.
847 Main Street
Buffalo, NY 14203
Phone: (716) 855-1068
Facsimile: (716) 855-1078

Date Prepared
December 19, 2003

Name of Device and Name/Address of Sponsor

SabreSource™ Drape
MINRAD INC.
847 Main Street
Buffalo, NY 14203

Device Name

Trade Name:	SabreSource™ Drape
Common Names:	Equipment Cover, Equipment Drape
Classification Name:	Light Beam Patient Position Indicator Accessory Surgical Drape and Drape Accessories

Predicate Devices

1) Microtek Medical, Inc. – Large C-Arm Drape Product Number 4982
2) Contour Fabricators Number CFI-600, equipment drape
3) MINRAD INC. – DRTS™ Drape

Intended Use

The SabreSource™ Drape is intended to help prevent contamination of the SabreSource™ device when used in the operating room or other surgical environments.

Technological Characteristics and Substantial Equivalence

The SabreSource™ Drape is a sterile plastic bag to cover the SabreSource™ Targeting System. The drape contains an optically clear window shaped like a section of a hemisphere with a 30 cm radius that will allow undistorted transmission of the laser beam from the SabreSource™ to the patient. Any dimensional or design differences between the SabreSource™ Drape and the predicate devices are minor and raise no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2004

Mr. John McNeirney
Vice President and CTO
MINRAD, Inc.
847 Main Street
BUFFALO NY 14203

Re: K041846
Trade/Device Name: SabreSource™ Drape
Model 301900
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical drape and
drape accessories
Regulatory Class: II
Product Code: 79 KKX
Dated: July 28, 2004
Received: July 30, 2004

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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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) you may obtain. 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SabreSource™ Drape
Indications for Use Statement

K041846

510(k) Number (if known):

This is an initial submission; no 510(k) number has been issued.

Device Name:

SabreSource™ Drape

Indications for Use:

The SabreSource™ Drape is to be used in an operating room environment to cover the SabreSource™ device when it is mounted on an x-ray machine for procedures wherein it is deemed desirable to protect the SabreSource™ device from contamination with patient fluids or liquids.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041846