K973162

MINRAD
DRTS™ Drape
510(k) Summary

NOV 20 1997

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

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Date Prepared:
August 21, 1997

Name of Device and Name/Address of Sponsor

DRTS™ Drape
MINRAD, Inc.
6576 East Quaker Street
Orchard Park, NY 14127

Device Name

Trade Name:	Dual Radiation Targeting System DRTS™ Drape
Common Names:	Equipment Cover, Equipment Drape
Classification Name:	Light Beam Patient Position Indicator Accessory

Predicate Devices

(1) Microtek Medical, Inc. -- Large C-Arm Drape Product Number 4982
(2) Contour Fabricators Number CFI-600, equipment drape

Intended Use

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

Technological Characteristics and Substantial Equivalence

The DRTS™ Drape is a sterile plastic bag to cover the DRTS™ Dual Radiation Targeting System. The drape contains an optically flat clear window that will allow undistorted transmission of the laser beam from the DRTS™ to the patient. Any dimensional or design differences between the DRTS™ 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

NOV 20 1997

Chris Healy
Hogan & Hartson
c/o Minrad, Inc.
6576 East Quaker St.
Orchard Park, NY 14127

Re: K973162
Dual Radiation Targeting System DRTS Drape
Dated: August 21, 1997
Received: August 22, 1997
Regulatory class: II
21 CFR 892.5780/Procode: 90 IWE
21 CFR 878.4370/Procode: 79 KKX

Dear Mr. Healy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MINRAD
510(K) Notification
DRTS™ Drape
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

K973162

Device Name:

DRTS™ Drape

Indications for Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973162

Prescription Use X
(Per 21 C.F.R. § 801.109)

Over-the-Counter Use ____