

K981115

JUN 25 1998

**510(k) SUMMARY:**

Rehabilitation Division

Smith & Nephew, Inc.  
One Quality Drive, P.O. Box 1005  
Germantown, WI 53022-8205 U.S.A.  
414-251-7840, Telefax: 414-251-7758

**Smith+Nephew**

Submitter: Rehabilitation Division  
Smith & Nephew, Inc.  
One Quality Drive  
N104 W13400 Donges Bay Road  
Germantown, WI 53022

Phone: (414)251-7840

FAX: (414)251-7758

Official Correspondent: Cordell C. Hoffins  
Correspondent phone: (414) 253-3069  
Date Prepared: March 23, 1998

Name of the Device: Thermoplastic for Radiotherapy Positioning  
Common name of Device: Immobilization and positioning device, for use in radiotherapy.  
Proprietary Name: Radio-plast  
Classification name: System, Radiation Therapy, Radionuclide  
Product Code: 90IWB  
Product Class: II

Legally marketed equivalent device:

MED-TEC, Inc. "Uni-Frame", K933227, in particular the "Aquaplast" splinting thermoplastic material used in this device.

Product Description: Radio-plast Thermoplastic Sheet Material for patient immobilization and positioning..

This device consists of a thermoplastic material which is intended to be used in a handling frame by radiotherapists in fabricating custom supports, positioning and immobilization devices for the head, neck, breast, neck and chest and foot, and other parts of the body. The device in its application consists of a conforming net of rigid thermoplastic material effecting immobilization. This thermoplastic material is intended for the fabrication of custom supports, positioning and immobilizing devices for use in radiotherapy.

The Rehabilitation Division, Smith & Nephew, Inc. thermoplastic material for the radiotherapy positioning application will consist of Radio-plast material in 1/16 inch (1.6mm), 3/32 inch (2.4mm) and 1/8 inch (3.2 mm) thicknesses, in various perforation patterns, with perforation percentages of 42%. Radio-plast will be marketed for both in sheets and in precut shapes to fit various frames designed by MED-TEC, Inc. and other suppliers currently on the market.



Intended use:

This device consists of a thermoplastic material which is intended to be used in a handling frame by radiotherapists in fabricating custom supports, positioning and immobilization devices for the head, neck, breast, neck and chest and foot, and other parts of the body during radiotherapy applications.

Intended use subject to 510(k) premarket notification:

The intended use of this device which is subject to premarket notification is fabrication of custom supports, positioning and immobilization devices for the head, neck, breast, neck and chest and foot, and other parts of the body for use during radiation therapy.

Technological Characteristics

The immobilizing characteristics of Radio-plast thermoplastics are substantially equivalent to the currently marketed "Aquaplast" splinting thermoplastics, and consist of the same material under different proprietary names.

Radio-plast (Aquaplast) has been shown in bio-compatibility studies to cause mild cytotoxicity and a weak potential for sensitization, and is substantially equivalent to the currently marketed Aquaplast splinting material.

Radio-plast thermoplastic is NOT sold as "Sterile".

Solid Radio-plast is approximately equivalent to 1.5 times its thickness of water, determined using a teletherapy type cobalt 60 beam.

Biocompatibility Testing Results

Biocompatibility testing of Radio-plast (Aquaplast) indicated that the thermoplastic material exhibits the following characteristics:

Cytotoxicity (Elution Test): Radio-plast (Aquaplast) meets the requirements of USP 23 and ISO 10993-5, and exhibited mild reactivity.

Cytotoxicity (Agar Diffusion Test): Radio-plast (Aquaplast) meets the requirements of USP 23 and ISO 10993-5, and exhibited slight reactivity.

FHSA Primary Dermal Irritation: Radio-plast (Aquaplast) was found to be non-irritating to the skin of New Zealand rabbits.

Dermal Sensitization (Magnusson, Kligman Maximization Test): Radio-plast (Aquaplast) was found to have a weak potential for sensitization.

Biocompatibility testing established that Aquaplast thermoplastic is substantially equivalent to the legally marketed thermoplastic, Aquaplast.

**Conclusion:**

Radio-plast thermoplastic is substantially equivalent to the legally marketed Aquaplast thermoplastic in radiotherapy immobilization applications.



JUN 25 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Cordell C. Hoffins  
Smith Nephew, Inc.  
One Quality Drive  
PO Box 1005  
Germantown, WI 53022-8205Re: K981115  
Radio-plast (Radiotherapy positioning device)  
Dated: March 23, 1998  
Received: March 2, 1998  
Regulatory class: II  
21 CFR 892.5050/Procode: 90 LHN  
21 CFR 892.5750/Procode: 90 IWB

Dear Mr. Hoffins:

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 requirements, 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/dsma/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

510(k) NUMBER (IF KNOWN): K981115

DEVICE NAME: RADIO - PLAST

INDICATIONS FOR USE:

These low temperature thermoplastic sheets may be used to fabricate custom positioning and immobilization devices for radiation therapy. These sheets may be formed directly against the patient's skin to produce immobilizer for any part of the body. The immobilizer should be used any time precise, repeatable positioning of a patient is required.

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

---

Concurrence of CDRH, Office of device regulation (ODE)

Prescription Use  OR Over-The-Counter-Use   
(Per 21 CFR 801.109) Optional Format 1-2-96

David A. Bergson  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K981115