JUL 1 2 2001

K003779

Premarket Notification [510(k)] Summary
Tab 4

DATE

Trade Name: Immobilization System for ENT

Common Name: Immobilization Devices for Head and Neck Radiation Therapy

Classification Name: Medical Linear Accelerator Accessory, 90 IYE (per 21 CFR section 892.5050)

Manufacturer's Name: Arplay Medical S.A.
Address: 1 Route de Citeaux
21110 Izeure
France

Corresponding Official: Richard Borgi, MD
Title: President and CEO
Telephone: +33-3-8029 7401
Fax: +33-3-8029 7622

Predicate: MED-TEC Uni-Frame Head Immobilization System, 510(k) # K933227

Device Description: The main components are a base plate manufactured from Perspex or carbon fiber, depending on the preference of the treating physician, thermoplastic mesh and a U shape frame with pins that is affixed to the base plate. The base plate can be attached directly to the table or attached to the Hyperextension headrest to facilitate hyperextension of the neck. Another option is to attach the U Shape Frame with thermoplastic mask to the Hyperflexion Mask Device to attain hyperflexion of the neck.

The thermoplastic is attached to the U Shape Frame with the pins and softened in a water bath of approximately 60 degrees Celsius. It is then gently stretched over the patient's head, attached to the base plate and allowed to cool and become rigid. After treatment the U Shape Frame is removed from the base plate. It will be used for each treatment to facilitate immobilization and duplicate head and neck position.

The Constraining Device for ENT Area can be used in conjunction with the U shape Frame, but is most often used to constrain patients who can not tolerate the thermoplastic mask. It has several repeatable adjustments to constrain the top of the head, the chin, bridge of nose, and/or mouth.

Intended Use: The Immobilization System for ENT is intended for use in constraining or immobilizing the head and neck of a patient during external beam radiation therapy.

Technological Characteristics: See the attached Predicate Comparison Table

#	Feature	Uni-Frame Head Immobilization System K933227	Arplay Medical Immobilization System for ENT
1	Rigid Baseplate	Lexan & Carbon Fiber	Perspex & Carbon Fiber
2	Perforated Thermoplastic	Yes	Yes
3	Reloadable U Frame	Yes	Yes
4	Hyperflexion Baseplate	Yes	Yes
5	Hyperextension Baseplate	No	Yes
6	Head Arch	Carbon Fiber	Perspex
7	Head Constraint	Multiple adjustments, Non Indexing	Multiple adjustments, With Indexing Scale
8	Headrests for Baseplate	Multiple sizes, Polyurethane	Multiple sizes, Polystyrene, Radiotransluscent
9	Standalone Headrests	Multiple sizes, Polyurethane	Multiple sizes, Polyurethane

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Richard Borgi, M.D.
President & CEO
Arplay Medical SA
1 Route DE Citeaux
21110 IZEURE, FRANCE

Re: K003779
Immobilization System for ENT
Dated: May 10, 2001
Received: May 17, 2001
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Dr. Borgi:

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 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). 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) 594-4639. 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 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,

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 (s)

Tab 3

Indications For Use

510(k) Number: K003779

Device Name: Immobilization System for ENT

Indications for Use:
Accessories to immobilize or constrain a patient during external beam radiation therapy of the head and neck.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K003779