NOV 2 0 2003

K032331

510(k) Summary

Summary of Safety and Effectiveness
Compliance with 513 (i) of the Federal Food, Drug and Cosmetic Act

Date Prepared: July 28, 2003

1. General Provisions

Classification Name:	Neurological Surgical Device
Common/Usual Name	**Neurosurgical Head Holder (Skull Clamp)**
Proprietary Name	• DORO® Radiolucent Headrest System • Radiolucent Horse Shoe Headrest Halo and • J-Arm Retractor System
Applicant Name and Address	PRO MED Instruments GMBH Bötzinger Str. 38 D79111 Freiburg Germany Attn: Edgar Schuele, Managing Director

1 of 4

000031

K032331

2. Name of Predicate Devices

Product	Clearance Number
pro med instruments GMBH DORO® Headrest System, Skull Pins and Halo Retractor System	K 001808
OMI MAYFIELD Radiolucent 2000 Skull Clamp	K 953124
J&J (CODMAN) Halo Split Ring Retractor System	(K913233)
Materials	
Spinal Concepts, Inc. SC-Acufix Thinline Anterior Plate System	K013979 (Laminated linen phenolic composite)
Buxton 77-1042 Mallet	Class 1 (Laminated linen phenolic composite)
Aesculap Modular Monopolar Electrodes	K970541 (PEEK coating is used on pro med instrument's DORO laminated linen phenolic)

3. Device Description

The DORO® Radiolucent Headrest System is a device system used as a support during head and neck surgery. It is composed of several components which are fabricated of materials that allow it to be radiolucent on x-ray. These components are:

1. the adjustable Base Unit,
2. the Skull Clamp, and
3. the Swivel Adaptor,
4. Horseshoe Headrest Adult and Children

2 of 4

It is suitable for use in adults and children when the appropriate components are selected.

The DORO System uses a three-point fixation of the head during surgery in the prone, supine, lateral, and sitting positions. The double clamping of the Adjustable Base unit provides simultaneous fixation of the lateral and vertical positions. The Crossbar is used for connection to the side rails of standard operating tables for fixation in a sitting position. The Swivel Adaptor is used in the base unit to provide 360 degree rotation.

The DORO Headrest System, except for the disposable Skull Pins, is sold non-sterile. The Base Unit, Swivel Adaptor and Skull Clamp are intended to be cleaned by the user between uses. It is intended to be used with Disposable, Skull Pins which were cleared with the DORO Headrest System (K001808).

The components of the DORO Headrest System are made of the following materials:

Skull Clamp is made of NOVOTEX laminated fabric with phenolic resin (GRP) colored with BASANTOL black X82 liqu1d and POM (Delrin), PEEK and Polyurethan.

The Swivel Adaptor and the Horseshoe Headrest in adult and pediatric versions, made of Novotex, PEEK and POM

The Base is made of Novotex, PEEK, POM and aluminum.

The J-Arm Retractor System is made of aluminum alloy and is not radiolucent.

The DORO Radiolucent Headrest System can also be used with accessories from the predicate DORO Headrest System (K001808) with Elastic Pads for adults, Headrest supports with one or two Elastic Pads, single Pin Holders, dual Pin Holders for adults, dual Pin Holders for children, a Multi-Purpose Skull Clamp with six Pin fixation or three Elastic Pads).

The DORO Radiolucent Headrest System can also be used with the J-Arm Retractor and Halo Retractor Assembly (K001808) which allows for use as a support and retraction device during neurosurgical procedures where retraction of the brain tissue and handrest are needed.

K032331

4. Classification

Neurosurgical Head Holders (Skull Clamps) are classified as class II devices according to 21 CFR 882.4460 (HBL). These devices are reviewed by the Neurological device panel.

A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold head and neck in a particular position during surgical procedures.

5. Performance Standards

Performance standards for sheath introducers have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

6. Intended Use and Device Description

The DORO® Radiolucent Headrest System is used as a support mechanism for head and neck surgery.

The DORO Non-Radiolucent J-Arm Retractor System is used as a component of the head and neck support during neurosurgical procedures to facilitate retraction of tissue is also required.

6. Biocompatibility

The radiolucent components of the system are intended to be used nonsterile. They do not contact the patient. These materials are NOVOTEX colored with BASF Basantal, POM and Polyurethan. No biocompatibility issues are raised.

7. Summary of Substantial Equivalence

The DORO® Radiolucent Headrest System is used as a head and neck support top stabilize a patient's head during neurosurgical operative procedures. This is the same use as the predicate pro med instruments GmbH DORO® Headrest System (K001808), and the OMI Mayfield Radiolucent 2000 Skull Clamp (K953124).

This device is similar in design, construction, intended use and performance characteristics to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

Pro Med Instruments GmbH
c/o Mr. Jim Bazzinotti
Vice President of Sales
Pro Med Instruments, Inc.
1899 Sawyer Lane
Alva, Florida 33920

Re: K032331
Trade/Device Name: DORO® Radiolucent Headrest System and Horseshoe Headrest
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical head holder (skull clamp)
Regulatory Class: II
Product Code: HBL
Dated: October 14, 2003
Received: October 16, 2003

Dear Mr. Bazzinotti:

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 (301) 594-4659. 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 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,

Miriam C. Provost

for 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

510(k) Number (if known): K032331

Device Name: DORO® Radiolucent Headrest System and Horseshoe Headrests

J-Arm Retractor System (Aluminum Alloy; Non-radiolucent)

Indications for Use:

The DORO Radiolucent Headrest System is used in open and percutaneous craniotomies and spinal surgeries for rigid cranial fixation and when intraoperative CT imaging is used.

The DORO® J-ARM Retractor Accessory is used to fix tissue retractor during neurosurgical procedures.

Miriam C. Provost

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

510(k) Number K032331

pro med instruments, Inc. 1899 Sawyer Lane
Alva, FL 33920 Tel: 1-877-225-4086 Fax: 239-225-4087