K063494

Appendix 1
510(k) Summary

MAY 2 1 2007

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

1. General Provisions

Date Prepared:	October 31, 2006
Classification Name:	Neurological Surgical Device
Common/Usual Name	Neurosurgical Head Holder (Skull Clamp)
Proprietary Name	DORO® Radiolucent / MRI Compatible Cranial Stabilization and Halo Systems (including DORO® Radiolucent / MRI Compatible Skull Clamp Headrest System with Skull Pins, DORO® Radiolucent / MRI Compatible Horseshoe Headrest Systems and DORO® Radiolucent / MRI Compatible Halo System)
Applicant Address	pro med instruments GmbH Bötzinger Str. 38 D79111 Freiburg / Germany
Applicant Name	Edgar Schuele, Managing Director

Predicate

Table – Predicate Devices

Applicant	Product	Clearance Number
pro med instruments GmbH	DORO® Radiolucent / MRI Compatible Skull Clamp Headrest System, including Disposable Skull Pins	K032331, K001808 Acucera, Inc. K051501xc
pro med instruments GmbH	DORO® Radiolucent / MRI Compatible Horseshoe Headrest Systems	K032331, K001808
pro med instruments GmbH	DORO® Radiolucent / MRI Compatible Halo Systems	K032331, K001808

Table – Predicate Materials

Materials	Applicant	Device	Clearance Number
Laminated linen phenolic composite	Spinal Concepts, Inc.	SC-Acufix Thinline Anterior Plate System	K013979
Laminated linen phenolic composite	Buxton 77-1042	Mallet System	Class 1
PEEK coating is used on pro med instrument's, laminated linen phenolic	Aesculap	Modular Monopolar Electrodes	K970541
zirconium stabilized with yttrium	ACUCERA, INC.	ZIRACE	K051501xc

2. Device Description

The DORO® Radiolucent / MRI Compatible Cranial Stabilization and Halo Systems are for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary (Skull Clamp with Skull Pins) or when secured non-invasive cranial stabilization (Horseshoe Headrest System) is required and when Intra-Operative CT or MR Imaging is used.

Main components (see also Appendix 2):

DORO® Radiolucent / MRI Compatible Cranial Stabilization and Halo Systems:

- DORO® Radiolucent / MRI Compatible Skull Clamp Headrest System with Skull Pins
- DORO® Radiolucent / MRI Compatible Horseshoe Headrest Systems
- DORO® Radiolucent / MRI Compatible Halo System

The DORO® Radiolucent / MRI Compatible Skull Clamp Headrest System uses a three-point fixation of the head during surgery in the prone, supine, lateral, and sitting positions via the radiolucent Skull Clamp with Skull Pins. The DORO® Radiolucent / MRI Compatible Horseshoe Headrest System is an alternative non-invasive gel-pad cranial stabilization system for prone and supine positioning. The Skull Clamp or Horseshoe Headrests can be connected to Swivel Adaptor which in turn can be connected to the appropriate Transitional Members (of varying lengths). These are all MR-Safe.

The Radiolucent Halo System is a series of radiolucent rings (full, half and quarter rings) with fixation rods to attach to the radiolucent skull clamp described above. It provides a hand rest for the Surgeon and a mounting place for a variety of surgeon tools, such as brain Retractor and a holding tray. The Halo Rings and the Rod Fixation Assembly are all MR-Safe.

The DORO® Radiolucent / MRI Compatible Cranial Stabilization and Halo Systems are sold non-sterile. The Swivel Adaptor, Skull Clamp and Horseshoe Headrests are intended to be cleaned by the user between uses. For rigid skeletal fixation, the Skull Clamp uses the disposable single-use ceramic (Yttried Zirconium) or Titanium Skull Pins, which are both x-ray and MRI-compatible.

The components of the DORO® Headrest Systems are made of the following materials (see also Appendix 2):

- The **Skull Clamp** is made of NOVOTEX laminated fabric with phenolic resin (GRP) colored with BASANTOL black X82 liquid and POM (Delrin), PEEK and Polyurethan. MR-Safe.
- The **Swivel Adaptor** and the **Horseshoe Headrest** in adult and pediatric versions, the Transitional Members and the Halo Systems are made of Novotex, PEEK and POM. MR-Safe.

- **DORO® Radiolucent Disposable Single-Use Skull Pins of Yttried Zirconium or Titanium** are X-ray and MRI compatible. MR-Safe.

The DORO® Radiolucent / MRI Compatible Cranial Stabilization and Halo Systems can be used with accessories from the predicate DORO® Headrest System (K001808) with Gel Pads for adults, Headrest supports with one or two Gel 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 Gel Pads.

4. Classification

DORO® Radiolucent / MRI Compatible Cranial Stabilization (Skull Clamp and Skull Pins) 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 with skull pins) is a device used to clamp the patient's skull to hold head and neck in a particular position during surgical procedures. A Horseshoe Headrest is a non-invasive method for cranial stabilization using Gel Pads. A Halo System is an arm rest for the surgeon or a mounting place for surgeons' tools.

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 Radiolucent / MRI Compatible Skull Clamp Headrest System with Skull Pins
The DORO® Radiolucent / MRI Compatible Skull Clamp Headrest System with Skull Pins are components of a mechanical support system which is used in head and neck surgery when rigid skeletal fixation is required for cranial stabilization and when intra-operative CT or MR Imaging is used.

The Radiolucent / MRI Compatible Horseshoe Headrest System
The DORO® Radiolucent / MRI Compatible Horseshoe Headrest System are components of a mechanical support system which is used in head and neck surgery when non-invasive head support is required and when intra-operative CT or MR Imaging is used.

The Radiolucent / MRI Compatible Halo System

The DORO® Radiolucent / MRI Compatible Halo System is a system of radiolucent halo rings of varying size and styles that may be used in neurosurgical applications as an arm rest during head and neck surgery when intra-operative CT or MR Imaging is required.

The intended use of this device is similar to the predicate pro med instruments GmbH DORO® Headrest System (K001808 and K032331), Ohio Medical Instrument Company, Inc.'s (OHIO medical Instrument Co., Inc.) "MAYFIELD Radiolucent 2000 Skull Clamp" (K953124) with the additional application of MRI-compatibility.

7. Biocompatibility

The Radiolucent components of the system are intended to be used non sterile. They do not contact the patient. These materials are NOVOTEX colored with BASF Basantal, POM and Polyurethan.
The DORO® Radiolucent Disposable Single-Use Skull Pins, Ceramic (Yttried Zirconium) and Titanium have contact with the patient, but there is no biocompatibility issues raised.

8. Summary of Substantial Equivalence

The DORO® Radiolucent / MRI Compatible Cranial Stabilization and Halo Systems and components are used as a head and neck support top stabilize a patient's head during neurosurgical operative procedures. It's the same use as the previous predicates of PMI.

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

P.5.d.5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Pro-Med Instruments GMBH
% Pro Med Instruments, Inc.
Mr. Edgar Schuele
5450 Lee Street, Suite 1
Lehigh Acres, FL 33971

MAY 2 1 2007

Re: K063494
Trade/Device Name: DORO® Radiolucent/MRI Compatible Cranial Stabilization and Halo Systems and accessories
Regulation Number: 21 CFR 882.4260
Regulation Name: Neurosurgical head holder (skull clamp)
Regulatory Class: II
Product Code: HBL
Dated: May 4, 2007
Received: May 7, 2007

Dear Mr. Schuele:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K063494

Device Names:

The **DORO® Radiolucent / MRI Compatible Cranial Stabilization and Halo Systems** includes:

- DORO® Radiolucent / MRI Compatible Skull Clamp Headrest System with Skull Pins,
- DORO® Radiolucent / MRI Compatible Horseshoe Headrest Systems,
- DORO® Radiolucent / MRI Compatible Halo System

Indications for Use:

The Radiolucent / MRI Compatible Skull Clamp Headrest System with Skull Pins
The DORO® Radiolucent / MRI Compatible Skull Clamp Headrest System with Skull Pins are components of a mechanical support system which is used in head and neck surgery when rigid skeletal fixation is required for cranial stabilization and when intra-operative CT or MR Imaging is used.

The Radiolucent / MRI Compatible Horseshoe Headrest System
The DORO® Radiolucent / MRI Compatible Horseshoe Headrest System are components of a mechanical support system which is used in head and neck surgery when non-invasive head support is required and when intra-operative CT or MR Imaging is used.

The Radiolucent / MRI Compatible Halo System
The DORO® Radiolucent / MRI Compatible Halo System is a system of radiolucent halo rings of varying size and styles that may be used in neurosurgical applications as an arm rest during head and neck surgery when intra-operative CT or MR Imaging is required.

Prescription Use: X **and /or** **Over-The Counter Use: NO**
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart (C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K063494