

K955397

APR 30 1996

Section B - Summary & Certification

**Summary of Safety and Effectiveness
Mayfield-ACCISS Workstation**

Pursuant to Section 513(i) of the Federal Food, Drug, and Cosmetic Act

I. General Information:

Classification Name: Stereotactic Instruments

Common/Usual Name: Computer-based stereotactic surgical planning system

Trade/Proprietary Name: Mayfield-ACCISS Workstation

Applicant's Name and Address:

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II. Name of predicate device(s):

ISG Allegro Viewing Wand (K911783)
Pelorus Arc Carrier (K851659A)
CORITechs CORITaxic I Workstation (K915791)
Cordis Micra Microsurgical Instruments (K862971) - *for use of Titanium in contact
with Brain Tissue*

III. Classification:

Neurosurgical stereotactic instruments and accessories are Class II (21 CFR 882.4560 Neurological Devices Panel).

IV. Performance Standards:

No applicable performance standards have been established by FDA under section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description:

Intended Use: ACCISS is to be used both for guidance and localization in open craniotomies and for surgeries which are traditionally performed with a stereotactic apparatus, such as biopsies, thalamotomies and electrode implants. The system may also be used to review medical images in a neurosurgical context.

Introduction: Stereotactic surgical systems superimpose on the patient a coordinate system which can be used to direct a probe or other surgical instrument, based upon diagnostic imaging information, to a predetermined point inside the cranium. When the point is established, surgical instruments are inserted in the instrument holder of stereotactic systems such as the BRW/CRW (K811452) or Leksell (Preamendments device) systems to biopsy and/or remove a lesion. Recently, systems have been developed which allow the determination of surgical paths without the use of a conventional stereotactic frame such as the ISG Viewing Wand (K911783).

The Mayfield-ACCISS™ Workstation is a computer-based system designed for use in the OR. It has a compact design, sterilizable keyboard cover and electrical isolation for patient safety. Completely self-contained on a cart, the system transfers easily between OR and offices for use not only as a clinical tool but as a desk-top based clinical research tool and image-review workstation as well. A simple yet direct user interface screen with easy-to understand graphics displays the images.

The Mayfield-ACCISS™ Workstation is intended to correlate a patient's preoperative Computed Tomography (CT) and/or Magnetic Resonance Image (MRI) data with a patient's anatomy to assist in planning and performing surgery. The system is composed of a medical imaging workstation and position-sensing articulated arm with a probe that acts as a localizing device. The workstation computer is loaded with the patient's CT or MRI data. The image data set is correlated to the patient on the OR table by physically matching points such as scanned fiducial markers, anatomical features or surface points with corresponding points on the imaged data set. After the correlation, the indication of the probe orientation appears on the screen and moves through the CT or MRI data in correct relation to the probe as manipulated by the surgeon.

The Mayfield-ACCISS™ Workstation consists of the following* :

- A. Workstation**
- B. Software**
- C. Probe Assembly**
- D. Pelorus Stereotactic System**

* The hardware configuration will be as stated or functionally similar.

E. Training Accessories

1 Plastic Skull

50 CT/MR Skin Markers

Supported Modalities

CT

MRI

Options:

Color Printer

9-Track Tape Drive

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VI. Summary of Substantial Equivalence*:

Indications: The indications for the Mayfield-ACCISS™ Workstation are the same as those for the predicate stereotactic devices.

Design: The design of the Mayfield-ACCISS™ Workstation is similar in concept to the predicate stereotactic devices.

Materials: The materials used in the manufacture of the hardware components of the Mayfield-ACCISS™ Workstation are similar to those used in the predicate devices. Material in direct, transient contact with central nervous system (CNS) tissue/fluids is ATSMB398-94 Grade 2 titanium. Titanium has been used in a number of devices which are transiently used in direct contact with CNS tissues/fluids, such as Cordis Micra Microsurgical Instruments (K862971). Therefore, OMI and NOMOS consider the use of titanium for the manufacture of the probe to be the same as the intended use for Microsurgical Instruments used for the direct brain contact. No new biocompatibility issues are raised. Differences in structural materials are addressed through labeling.

Manufacturing: The manufacturing processes used in the Mayfield-ACCISS™ Workstation are similar to those used in the manufacture of predicate stereotactic devices.

Specifications: The specifications of the Mayfield-ACCISS™ Workstation are similar to those of the predicate stereotactic device.

Conclusions: The indications, design, materials, manufacturing, and specifications of the Mayfield-ACCISS workstation do not raise any new unresolved issues relating to safety and effectiveness.

NOMOS thus considers the Mayfield-ACCISS™ Workstation substantially equivalent to the predicate devices.

***Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without premarket approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, ". . . a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without premarket approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits." 42 Fed. Reg. 42,520 et seq. (1977).**