K946033

SEP - 1 1995

ATTACHMENT 8

Statement of Safety and Effectiveness Information

Submitter's name, address, telephone number and contact person:

Leibinger LP
14540 Beltwood Parkway East
Dallas, Texas 75244

Contact: Andrew B. Rogers
(214) 392-3636
(214) 392-7258 (fax)

Name of the device:

The Stereoplan Plus Software Package for the Planning of Stereotactic Treatment of Intracerebral Lesions (the "Stereoplan Plus system").

Classification name:

Accessory to Stereotaxic Instrument (21 C.F.R. § 882.4560)

Predicate device:

Leibinger STP Complete Module Set for Planning of Stereotactic Treatments (K892425/D)

Description of the device:

Stereoplan Plus is a software tool intended to help the surgeon plan stereotactic treatments. It enables the user to select optimally fitting stereotactic catheter positions by digitizing the entry (trephination) and target points of the catheter needle If both points define a needle which can be set on the operating device, the corresponding angles are calculated and displayed in the needle window. Any needle can be defined and displayed in CT slices or sections or angiographic images if they are available. Needles are always stored in stereotactic coordinates and can be digitized and displayed in any space of patient's images (CT, MR or Angiographic). The software can project the selected needle to any slices or sections and generate surgeon's eye views. For any possible needle position, the angle settings for either the Riechert/Mundinger or Zamorano/Dujovny stereotactic operating devices can be displayed.

Stereoplan Plus supports the transfer of stereotactic coordinates between angiographic, CT and MR images. Regions of Interest ("ROIs") and Volumes of Interest ("VOIs") can be defined, transferred and displayed between angiographic, CT and MR images. Their area and volume can be calculated.

There are two major components of the Stereoplan Plus system: the hardware utilized to position and restraint the patient's head; and the software used to position the hardware.

Intended use of the device:

The Stereoplan Plus system is intended to be used in planning stereotactic treatment of intracerebral lesions. Specifically, the Stereoplan Plus system is intended for planning stereotactic punctures. This indication for use is cleared for the predicate device, the STP Complete Module Set, also developed and marketed by Liebinger under K892425/D.

Comparison of the device's technological characteristics with those of the predicate device:

The functionality of the Stereoplan Plus system is identical to the corresponding functionality of the predicate STP system and raises no new issues of safety and effectiveness. This is because the function implemented by the Stereoplan Plus system is one of the three functions already implemented by the STP system. The only differences between the systems are the result of advances in available technology. Indeed, the process and the software functions are the same, but the Stereoplan Plus utilizes a 486-compatible PC platform where the STP system runs on VAX-compatible workstations. The stereotactic hardware utilized by both systems is identical.

The software component of the Stereoplan Plus system is substantially identical to the corresponding portions of the predicate STP system software. As discussed above, the Stereoplan Plus software is merely a subset of the STP software, performing planning of one of the three different stereotactic procedures supported by the STP system. The only difference is the development environment of each system, representing advances made in the technology of the underlying platforms of each system. The Stereoplan Plus system software was written in the C++ language, and the STP software was written in VAX Fortran (an enhanced version of Fortran 77). Therefore, the Stereoplan Plus system software raises no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

SEP - 1 1995

Re: K946033
Stereoplan Plus Software Package
Dated: July 7, 1995
Received: July 7, 1995
Regulatory Class: II (two)
Product Code: 84 HAW

Mr. Howard M. Holstein
Leibinger GMBH
c/o Hogan & Hartson
Columbia Square
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Dear Mr. Holstein:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act

may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

2