JUN 1 1998

K981398

510(k) Summary

AnatoMark™ Noninvasive Head Reference System

Common/Classification Name: Accessory to MR Imaging System, 21 CFR 892.1000

Interneuron Pharmaceuticals, Inc.
99 Hayden Avenue, Suite 200
Lexington, MA 02173

Telephone: 781-861-8444
FAX: 781-863-2564

Contact: Sonja Loar, Pharm.D., Prepared: April 8, 1998

A. LEGALLY MARKETED PREDICATE DEVICES

The AnatoMark Noninvasive Head Reference System is an accessory to MR devices (21 CFR 892.1000). It shares some features with the Laitinen Stereoadapter 5000 (K881131), cleared as a stereotaxic instrument (21 CFR 882.4560), and the Codman Fiducial Marker System (K953568), cleared as a radiographic film marker (21 CFR 892.1640).

B. DEVICE DESCRIPTION

The AnatoMark Noninvasive Head Reference System is a simple device, worn externally on the head, designed for use in routine head or brain MRI to provide reference markers that are visible on magnetic resonance (MR) images.

The AnatoMark Noninvasive Head Reference System is intended to provide fiduciary marks that are visible on magnetic resonance (MR) images. The device may also be used to provide MRI/CT co-registration of fiduciary marks. The device is worn externally on the head, is simple and non-invasive, and wearing it is somewhat similar to the wearing of eyeglasses.

The device is intended to be used with the "scout" or localization image sequence to establish a reproducible reference plane within the MR system's imaging coordinate system for the subsequent imaging session. At each of three reference locations on the device there is a reference block that contains two reference tubes that appear on MR images. The reference marks are physically implemented as cylinders set in the reference block such that they are orthogonal to each other and cross at their midpoints. When imaged slightly out of plane of the midpoints, the cross-sections of the small cylinders appear as two fiduciary marks that are not side by side. When imaged in the plane of the midpoints,

however, the fiduciary marks are side by side. By adjusting the plane of the images such that all three pairs of reference marks show side by side, a reproducible reference plane may be established.

C. INTENDED USE

The AnatoMark Noninvasive Head Reference System is an accessory for routine head MR that is designed to provide reproducible anatomical markers. The Head Reference System is designed to aid in patient positioning to achieve consistent anatomical images over multiple imaging sessions. The head localizer produces a set of six fiduciary marks on axial images that are positioned reproducibly with reference to stable anatomical structures internal to the patient's cranium. The fiduciary marks are also visible in CT images, making possible the co-registration of CT and MR images.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **AnatoMark Noninvasive Head Reference System** does not have the identical indications for use as the predicate devices, but it has the same intended use. The **AnatoMark Noninvasive Head Reference System** has the same technological characteristics as the predicate devices.

The descriptive characteristics may not be precise enough to assure equivalence, so Interneuron Pharmaceuticals has carried out performance testing to assure equivalence. The resulting performance data do, in fact, demonstrate equivalence. The flowchart for the substantial equivalence algorithm leads to a substantial equivalence decision.

E. TECHNOLOGICAL CHARACTERISTICS

The **AnatoMark Noninvasive Head Reference System** has the "same technological characteristics" as the Laitinen Stereoadapter 5000. Both provide reference markers that are made of materials that can be easily visualized on MR images.

F. TESTING

Interneuron Pharmaceuticals has carried out testing of the device to demonstrate that it provides reproducible reference markers. This testing indicated that the accuracy is substantially equivalent to the accuracy of the predicate device.

G. CONCLUSIONS

This 510(k) has demonstrated that the **AnatoMark Noninvasive Head Reference System** is substantially equivalent to presently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 1 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sonja Barton Loar
V.P. Regulatory & Scientific Affairs
Interneuron Pharmaceuticals, Inc.
99 Hayden Avenue, Suite 200
Lexington, MA 02173

Re: K981398
Head Reference System (MRI/CT Anatomical Marker)
Dated: April 15, 1998
Received: April 17, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Ms. Loar:

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 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) 594-4613. 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" (21 CFR 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K981398

Device Name: AnatoMark Noninvasive Head Reference System

Indications For Use:

The AnatoMark Noninvasive Head Reference System is an accessory for routine head MR that is designed to provide reproducible anatomical markers. The Head Reference System is designed to aid in patient positioning to achieve consistent anatomical images over multiple imaging sessions. The head localizer produces a set of six fiduciary marks on axial images that are positioned reproducibly with reference to stable anatomical structures internal to the patient's cranium. The fiduciary marks are also visible in CT images, making possible the co-registration of CT and MR images.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981398

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)