K100038

JUL 14 2010

510 (k) Summary
Disposable Reflective Marker Spheres

Manufacturer:

Address:	BrainLAB AG Kapellenstrasse 12 85622 Feldkirchen Germany
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Contact Person:	Mr. Alexander Schwiersch

Summary Date: Mar. 09, 2010

Device Name:

Trade name:	**Disposable Reflective Marker Spheres**
Common/Classification Name:	Disposable Reflective Marker Spheres
Regulation number:	21 CFR 882.4560
Product codes:	HAW, OLO

Predicate Device:
Cranial Image Guided Surgery System K082060

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II

This submission does not change the indications for use for the predicate devices.

1. Intended Use:
Disposable reflective marker spheres are attached to reference arrays and instruments, thus enabling the infrared tracking systems to detect the position of the patient and instruments in the surgical field.

2. Device Description:
A disposable reflective marker sphere consists of two bonded half spheres and a screw part that is cut in the lower sphere. An adhesive combines the upper and lower half spheres. The raw sphere is covered with a defined retro-reflective foil.

3. Verification:
To ensure that all specifications of the device have been implemented correctly, following essential requirements have been verified successfully:
- Crucial physical properties of the device (e.g. Impact resistance, homogenous retro-reflectivity, shelf life)
- Sterile Packaging
- Sterilization

4. Validation:
Objective evidence that device specifications conform with user needs and intended use has been made by representative literature research, comparison with previously marketed devices and the results of a clinical evaluation.

5. Substantial equivalence:
The Disposable Reflective Marker Spheres have been verified and validated according to BrainLAB's procedures for product design and development. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device Cranial Image Guided Surgery System (K082060).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BrainLAB AG
% Mr. Alexander Schwiersch
Regulatory Affairs Manager
Kapellenstrasse 12
85622 Feldkirchen, Gemany

JUL 1 4 2010

Re: K100038
Trade/Device Name: Disposable Reflective Marker Spheres
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW, OLO
Dated: July 02, 2010
Received: July 08, 2010

Dear Mr. Schwiersch:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100038

Device Name: Disposable Reflective Marker Spheres

Indications For Use:

Disposable reflective marker spheres are attached to reference arrays and instruments, thus enabling infrared tracking systems to detect the position of the patient and instruments in the surgical field.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100038

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)