FEB - 7 2011

K 103192

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS IN ACCORDANCE WITH SMDA OF 1990

DATE OF APPLICATION:
2010-10-22

Submitted by: ILUMARK GmbH
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Germany
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Contact Person: Holger-Claus Rossner

1. Device Name

Trade Name: ILUMARK Navigation Marker Snap; ILUMARK Navigation Marker Twist
Common Name: Navigation Marker
Classification Name: Neurological Stereotaxic Instrument

2. Classification

Device:	neurological stereotaxic instrument	Orthopedic stereotaxic instrument
Medical Specialty:	Part 882, Neurological Devices	Part 882, Neurological Devices
Product Code:	84 HAW	84 OLO
Regulation Number:	882.4560	2
Device Class:	2	882.4560

3. Substantial Equivalence

ILUMARK's navigation Markers are substantial equivalent based upon their intended use, design, dimensional and materials characterization to other legally marketed devices from different manufacturers, e.g. NDI passive Spheres from Northern Digital Inc., #K033621 and Disposable Reflective Marker Spheres from BrainLAB Ag #K100038.

4. Description of the Device

ILUMARK Navigation Markers are used as accessories with image guided surgery systems. The Navigation Markers define specific locations on instruments and reference geometries. A camera system, as part of an image guided surgery system uses the location information to determine the orientation and location of an instrument relative to other instruments or reference geometries. A computer system visualizes the orientation and location of the instrument based on pre-operative data or a computer calculated model of the patients anatomy.

5. Intended Use

ILUMARK Navigation Markers are intended to be used as image guided surgery system accessory to aid in auto-registration and localization of rigid patient anatomical structure in either open or percutaneous image guided surgery procedures. It is indicated for any medical condition in which the use of an image guided surgery system may be considered to be appropriate.

ILUMARK Navigation Markers can be used in following procedures:

- Stereotactic brain surgery
- Endoscopic Sinus Surgery
- Pedicle Screw Placement
- Reconstructive orthopedic surgery
- Soft tissue treatment

6. Sterilization

ILUMARK Navigation Markers are sterilized with Ethylene oxide vacuum cycle, using 100% EtO. The sterilization process has been validated under consideration of an SAL 10^{-6} according to the requirements based on ISO 11135-1 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (in accordance with ISO 13060 / ISO 17665) in consideration of the respective national requirements.

7. Conclusion

Based on the available 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that ILUMARK's Navigation Markers are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

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

Ilumark GmbH
% Medagent GmbH
Mr. Andre Weingerl
Griesweg 47
Muhlheim, Germany 78570

FEB - 7 2011

Re: K103192
Trade/Device Name: Navigation Marker Snap; Navigation Marker Twist
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW, OLO
Dated: December 20, 2010
Received: December 27, 2010

Dear Mr. Weingerl:

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,

for

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: K 103192

Device Name:

Navigation Markers Snap, Twist

Indications for Use:

ILUMARK Navigation Markers are intended to be used as image guided surgery system accessory to aid in auto-registration and localization of rigid patient anatomical structure in either open or percutaneous image guided surgery procedures. It is indicated for any medical condition in which the use of an image guided surgery system may be considered to be appropriate.

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Prescription Use __**YES**___ AND/OR Over-The-Counter Use __**NO**__
(Part 21 CFR 801 Subpart D) (21 SFR 801 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103192