F K111443

PREMARKET NOTIFICATION 510 (K) SUMMARY

SEP 2 9 2011

1. **Submitters Name:** Dancho Jordanov

2. **Address:** X12 Co., Ltd.
J&L Center, fl.4, rm.403
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1618 Sofia
Bulgaria

3. **Telephone No:** +359 878 350 021
Fax:

4. **Date Prepared:** April 28, 2011

5. **Trade Name:** X12 Sterile Reflective Marker Sphere

6. **Common Name:** Disposable Reflective Marker Sphere

7. **Classification Name:** Neurological Stereotaxic Instrument
Orthopedic Stereotaxic Instrument

8. **Predicate Devices:** X12's Sterile Reflective Marker Spheres are substantially equivalent to those legally marketed by BrainLAB AG, Norhern Digital Inc. and ILUMARK GmbH (see table, below). This is based upon their intended use, design and materials of construction.

Name	Common Name	Product Code	510(k) Number	Date
BrainLAB AG	Disposable Reflective Marker Spheres	HAW, OLO	K100038	July 14, 2010
Northern Digital	NDI Passive Spheres	HAW	K033621	January 27, 2004
ILUMARK GmbH	Navigation Marker	HAW, OLO	K103192	February 7, 2011

9. **Device Description:**

X12's Sterile Reflective Marker Spheres consist of two hemispheres, coated with a retro-reflective foil, bonded together on a central pin to form a sphere. The central pin can be threaded with an M3 female thread or have a snap hole to mate with a mounting pin. The retro-reflective foil is applied in such a way as to provide reflectivity from all angles that is equivalent to the

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predicate devices. The spheres are individually packaged in a special sterile package and are gamma sterilized.

10. **Indications For Use:**

Passive Retro-Reflective Markers, disposable, used as an accessory to aid in the auto-registration and localization of rigid patient anatomical structures in either open or percutaneous image guided surgical procedures.

11. **Performance Testing:**

X12's Sterile Reflective Marker Spheres were tested to verify their retro-reflectivity in comparison to the predicate devices. Both the polar and equatorial views showed retro-reflectivity that was equivalent to the predicate devices.

A water soak test was conducted to show that the markers maintain there mechanical properties after being soaked in water. A surface abrasion test was performed which showed that the surface durability was substantially equivalent to the predicate devices.

12. **Sterilization:**

X12's Sterile Reflective Marker Spheres are inserted (6 each), in special "made for sterilization" plastic shells which are sealed in a nitrogen environment in plastic sterilization packets. Each packet is inserted in a box and is gamma sterilized in a carton containing 50 boxes. Each box is printed with pertinent labeling which includes the date of manufacture, expiration date, manufacturer batch and sterilization lot numbers and the manufacturer's name and address, as well as instructions for use.

13. **Conclusion:**

Based on the available 510 (K) summaries and statements and the information provided here, we conclude that X12's Sterile Reflective Marker Spheres are substantially equivalent to the predicate devices which are legally marketed in the United States under the FDA regulations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –W066-G609
Silver Spring, MD 20993-0002

Pinsco Inc. dba B & L Engineering
% Mr. Lee A. Barnes
1901 Carnegie Avenue, Suite Q
Santa Ana, California 92705

SEP 29 2011

Re: K111443
Trade/Device Name: X12 Sterile Reflective Marker Sphere
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, HAW
Dated: September 07, 2011
Received: September 12, 2011

Dear Mr. Barnes:

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: K111443

Device Name: X12 STERILE REFLECTIVE MARKER SPHERE

Indications for Use:

Used as an accessory to aid in the auto-registration and localization of rigid patient anatomical structures in either open or percutaneous image guided surgical procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

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

510(k) Number K111443