K120796

superDimension

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510(k) Summary

OCT 2 6 2012

superDimension® superLock Cobra fiducial marker

Submitter Information	
Name	superDimension, Ltd.
Address	161 Cheshire Lane, Suite 100 Minneapolis MN 55441
Telephone number	763.210.4000
Facsimile number	763.210.4098
Establishment Registration Number	3004962788
Name of contact person	Karyl Haskell Vice President of Quality and Regulatory Affairs
Date prepared	March 14, 2012
Trade or proprietary name	superDimension® superLock Cobra
Common or usual name	Fiducial Marker
Classification name	Marker, Radiographic, Implantable
Classification panel	Radiology
Regulation/Product Code	21 CFR Part §892.1750 / JAK
Legally marketed device(s) to which equivalence is claimed	510(k) K031206 RadioMed Visicoil (JAK 21 CFR §892.1750) 510(k) K100267 Cortex Manufacturing Fleximarc IYE 21 CFR §892.5050) 510(k) K093064 Somatex Tumark Professional (NEU 21 CFR §878.4300)
Device description	The superDimension superLock Cobra is an implantable marker intended to be used to radiographically mark soft tissue for future surgical or therapeutic purposes. The marker is placed at or near the intended treatment site and can easily be visualized in subsequent imaging studies. The location of the treatment area is identified with respect to the marker. The superDimension superLock Cobra is manufactured of gold and nitinol. The marker is delivered in a sterile pre-loaded delivery cartridge. The device is intended for single use.
Intended use of the device	The superDimension superLock Cobra is intended to be used to radiographically mark soft tissue for future surgical or therapeutic purposes.
Technological characteristics	The superDimension superLock Cobra has the same technological characteristics as the predicate device(s) in terms of the design and materials. The predicate devices are gold or nitinol; whereas the superDimension device is nitinol/gold.
Performance Tests	Tests were performed to demonstrate substantial equivalence of the superDimension device in comparison to the predicated as follows: • Radiographic Visibility • Compatibility with imaging equipment (Cyberknife, OBI) • Migration resistance
Conclusions	The results of the nonclinical tests demonstrate that the superDimension superLock Cobra is as safe and effective as the legally marketed predicate devices, and performs as well as or better than the predicate device(s).

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

OCT 2 6 2012

Mr. Karyl Haskell
Vice President, Quality and Regulatory Affairs
superDimension, Inc.
161 Cheshire Lane, Suite 100
MINNEAPOLIS MN 55441-5433

Re: K120796
Trade/Device Name: superDimension superLock Cobra
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 3, 2012
Received: October 4, 2012

Dear Mr. Haskell:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: superDimension superLock Cobra

Indications For Use: The superDimension superLock Cobra is intended for use to radiographically mark soft tissue for future surgical therapeutic procedures.

The superLock Cobra is contraindicated as follows:

- No more than 10 devices should be used per patient
- Devices should not be used in an MRI machine with magnetic coils that exceed 3T

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K120796