DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 28, 2017

Cook Incorporated
Ms. Erum Nasir, MS
Regulatory Affairs Team Lead
750 Daniels Way
Bloomington, Indiana 47404

Re: K170008
Trade/Device Name: Osteo-Site Bone Biopsy Needle, Osteo-Site Bone Biopsy Needle Set
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: December 30, 2016
Received: January 3, 2017

Dear Ms. Nasir:

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 and Part 809), please contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K170008

Device Name
Osteo-Site® Bone Biopsy Needle and the Osteo-Site® Bone Biopsy Needle Set

Indications for Use *(Describe)*
The Osteo-Site® Bone Biopsy Needle and Osteo-Site® Bone Biopsy Needle Set is intended for vertebral body access, biopsy and infusion during a vertebroplasty procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 2.0 510(k) SUMMARY

**Osteo-Site® Bone Biopsy Needle and the Osteo-Site® Bone Biopsy Needle Set**
**21 CFR §807.92**
**Date Prepared: December 30, 2016**

**Submitted By:**

| | |
|---|---|
| Submission: | Traditional 510(k) Premarket Notification |
| Applicant: | Cook Incorporated |
| Contact: | Erum Nasir, MS |
| Applicant Address: | Cook Incorporated<br>750 Daniels Way<br>Bloomington, IN 47404 |
| Contact Phone Number: | (812) 335-3575 x102607 |
| Contact Fax Number: | (812) 332-0281 |

**Device Information:**

| | |
|---|---|
| Trade Name: | **Osteo-Site® Bone Biopsy Needle and the Osteo-Site® Bone Biopsy Needle Set** |
| Common Name: | Instrument, Biopsy |
| Classification Name: | Gastroenterology-Urology Biopsy Instrument |
| Classification Regulation: | 21 CFR §876.1075, Product Code KNW |
| Device Class/Classification Panel: | Class II, Gastroenterology/Urology |

**Predicate Devices:**

- Stryker Bone and Vertebral Body Biopsy Kit (K032943)

**Device Description:**

The Osteo-Site® Bone Biopsy Needle and Osteo-Site® Bone Biopsy Needle Set consists of a cannula with an accompanying inner stylet and an obturator. The device may include an additional inner biopsy needle and obturator. The cannula is available in several sizes (11, 13 or 15 gauge) and lengths (10 or 15 cm) with various cannula/stylet tip configurations. The additional inner biopsy needle is available in two sizes (14 or 16 gauge) and lengths (17.1 or 22.1 cm) with a trephine tip and functions coaxially with the cannula once the stylet is removed. A plastic, non-radiopaque needle holder is also available to aid with needle placement.

**Intended Use:**

The Osteo-Site® Bone Biopsy Needle and Osteo-Site® Bone Biopsy Needle Set is intended for vertebral body access, biopsy and infusion during a vertebroplasty procedure.

**Comparison to Predicate Devices:**

The Osteo-Site® Bone Biopsy Needle and Osteo-Site® Bone Biopsy Needle Set is substantially equivalent to the predicate device, the Stryker Bone and Vertebral Body Biopsy Kit (K032943), in that these devices have similar indications for use, technological characteristics, design, and method of placement. The differences between the subject devices and the predicate devices are shown in the table below and include the materials, dimensions, cannula/stylet tip configurations, sterilization method, and included components. These minor differences were appropriately assessed and do not raise new questions regarding safety or effectiveness.

**Substantial Equivalence Table**

| | **Stryker Bone and Vertebral Biopsy Kit (K032943)** | **Osteo-Site® Bone Biopsy Needle and Set - Proposed Device** |
|---|---|---|
| **Regulation** | 876.1075 | Identical |
| **Product Code** | KNW | Identical |
| **Classification** | II | Identical |
| **Intended Use** | Stryker's bone and vertebral body biopsy kits can be used as a biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using a coring, cutting or aspiration technique. | This device is intended for vertebral body access, biopsy and infusion during a vertebroplasty procedure. |
| **Ancillary Device Information** | Stryker Introduction Cannula/Stylet is sold separately, but required to access the vertebral body to perform a biopsy with the Stryker Bone and Vertebral Biopsy Kit | N/A<br>The Cannula/Stylet combination is included as a component in the Osteo-Site® Bone Biopsy Needle Set and is subject of this submission. |
| **Anatomical Site** | Vertebral Body | Identical |
| **Method of Placement** | Percutaneous | Identical |
| **Biopsy technique** | Coring/Cutting/Suction | Not specified |
| **Biopsy Component** | Inner Biopsy Needle | Cannula/Inner Biopsy Needle* |

* The proposed set includes the inner biopsy needle and obturator.

**Substantial Equivalence Table (cont'd)**

| | | Stryker Bone and Vertebral Biopsy Kit (K032943) | Osteo-Site® Bone Biopsy Needle and Set - Proposed Device |
|---|---|---|---|
| **Cannula**** | **Material** | Stainless Steel | Identical |
| | **Gauge** | 10, 11, 13 | 11, 13, 15 |
| | **Length (cm)** | 12.7 | 10, 15 |
| | **Tip Configuration** | Four-Facet | Tapered, Bevel, Franseen |
| **Stylet**** | **Material** | Stainless Steel | Identical |
| | **Tip Configuration** | Diamond, Bevel | Scoop, Trocar, Bevel, Diamond |
| **Inner Biopsy Needle*** | **Material** | Stainless Steel | Identical |
| | **Gauge** | 10, 11, 13 | 14, 16 |
| | **Length (cm)** | 12.7, 22.9 | 17.1, 22.1 |
| | **Tip Configuration** | Four-Facet | Trephine |
| **Obturator*** | **Material** | Stainless Steel | Identical |
| | **Number** | One | One or Two |
| **Handle Material** | | Unknown | ABS/Polycarbonate |
| **Accessories** | | Syringe | Needle Holder |
| **Obturator Material** | | Stainless Steel | Identical |
| **Sterilization Method** | | Gamma Irradiation, VDmax25 | EtO |
| **Sterilization Assurance Level** | | $10^{-6}$ | $10^{-6}$ |
| **Packaging** | | Peel pouch | Tyvek peel pouch |

* The proposed set includes the inner biopsy needle and obturator.
** Stryker Introduction Cannula/Stylet is listed under product code OAR and sold separately, but is required to access the vertebral body to perform a biopsy with the Stryker Bone and Vertebral Biopsy Kit cleared under K032943. Predicate IFU and brochure is provided in Appendix B (Page B-6 and B-9, respectively) for reference purpose only.

## Performance Data:

The following tests were performed to demonstrate that the proposed Osteo-Site® Bone Biopsy Needle and Osteo-Site® Bone Biopsy Needle Set met the applicable design and performance requirements and support a determination of substantial equivalence. Where applicable, testing was done per applicable ISO and other international standards.

- Compatibility and Dimension Analysis (Cannula, Stylet, Obturator, Inner biopsy needle, Inner biopsy needle obturator) - Testing demonstrated that the devices function as intended.

- Tensile Testing (Cannula, Stylet, Obturator, Inner biopsy needle, Inner biopsy needle obturator, and Needle holder) – Testing demonstrated that the devices withstand peak load values greater than the predetermined acceptance criterion.
- Torque Strength Testing (Cannula, stylet, Inner biopsy needle) – Testing demonstrated that the devices withstand torque forces greater than the predetermined acceptance criterion.
- Torsional Override Testing (Cannula) - Testing demonstrated that the devices withstand torsional load greater than the predetermined acceptance criterion.
- Compression Strength Testing (Cannula and stylet assembly, Inner biopsy needle) – Testing demonstrated that the devices withstand compression forces greater than the predetermined acceptance criterion.
- Resistance to Breakage Testing (Cannula and stylet assembly)– Testing demonstrated that the devices function as intended.
- Biopsy Testing (Cannula and inner biopsy needle) – Testing demonstrated that the devices function as intended.
- Biocompatibility Testing – Testing (cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemolysis, partial thromboplastin time, and complement activation) shows that the devices are biocompatible.

**Conclusion:**

The results of these tests support a conclusion that the Osteo-Site® Bone Biopsy Needle and Osteo-Site® Bone Biopsy Needle Set met the design input requirements based on the intended use and support the conclusion that this device does not raise new questions of safety or effectiveness and is substantially equivalent to the predicate device, Stryker Bone and Vertebral Body Biopsy Kit (K032943).