510(k) SUMMARY
Stryker KWIC Needle

May 30th, 2014

JUN 05 2014

510(k) Number: K140868

1. **Contact Person**

John Urtz
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77 Great Valley Parkway
Malvern, PA 19355
(t) 610-640-7450 – (f) 484-323-8803

2. **Device Name and Classification**

Product Name:	Stryker KWIC Needle
Classification Name:	Neurologic Stereotaxic Instrument, Biopsy Instrument, Biopsy
Common or Usual Name:	Stereotaxic Instrument Gastroenterology-urology Biopsy Instrument
Regulation Number:	882.4560 876.1075
Reviewing Panel(s):	Surgical Devices Gastroenterology/Urology
Device Class:	Class II
Product Code:	HAW KNW

3. **Predicate Device(s)**

Orthovita Inc.'s Imbibe Needle (K050795)
Stryker Leibinger's Navigation System Spine & Fluoroscopy Module (K012380)

4. **Device Description**

The Stryker KWIC (K-wire Insertion Cannulated) Needle is a manually operated needle that is used to assist in the placement of guidewires (e.g. K-wires) and/or the aspiration of autologous blood or bone marrow for orthopedic surgery. The Stryker KWIC Needle is designed to interface with already-cleared Stryker navigation systems.

This device is to be manually calibrated and used with Stryker navigation systems. This device is intended to be used in spine applications to perform general manual functions within the orthopedic environment including the placement of guidewires (e.g. K-wires) or to draw bone

marrow. Guidewires may be used to place other hardware utilized in orthopedic procedures including pedicle screws.

5. **Indications for Use**
The Stryker KWIC Needle is a manual surgical instrument intended to be used in spine surgery to facilitate placement of guidewires. The device may also be used to aspirate autologous blood or bone marrow by use of a syringe. The blood or bone marrow may be combined with bone graft or bone void filler.

The Stryker KWIC Needle may be used as part of a planning and intraoperative guidance system to enable open or percutaneous image guided surgery. The KWIC Needle is indicated for use in spinal surgical procedures in which the use of image guided surgery may be appropriate, and where a reference to a rigid anatomical structure, such as the skull or vertebra, can be identified relative to medical images.

6. **Substantial Equivalence**
Information within this submission supports substantial equivalence. The indications for use contain the indications of the predicate Imbibe Needle and the device description notes compatibility with previously cleared Stryker Navigation Systems. Furthermore, the indication for placing guidewires in orthopedic surgery is typically performed by similarly designed Class I instruments, therefore this additional indication is acceptable for the Stryker KWIC Needle.

The materials and construction of the Stryker KWIC Needle are nearly identical to the predicate Imbibe Needle; therefore, preclinical testing performed utilizing the predicate including simulated bone marrow aspiration and mechanical testing similarly applies to the Stryker KWIC Needle.

7. **Performance Data**
Preclinical bench testing utilizing the Stryker KWIC Needle was performed by way of simulated cadaveric testing including guidewire placement. Further, functionality with the Stryker Navigation System was confirmed. The results from this testing demonstrate that the Stryker KWIC Needle is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 5, 2014

Orthovita Incorporated
Mr. John Urtz
Senior Regulatory Affairs Specialist
77 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K140868
Trade/Device Name: Stryker KWIC Needle
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW, KNW
Dated: April 3, 2014
Received: April 3, 2014

Dear Mr. Urtz:

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 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" (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 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,

David Krause -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

Indications for Use Statement

510(k) Number (if known): K140868

Device Name: Stryker KWIC Needle

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

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

Concurrence of CDRH, Office of Device Evaluation

Neil R Ogden -S
2014.06.05 12:31:09 -04'00'

For BSA