



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

Orthovita Incorporated
Ms. Lynn Lundy, MBA, RAC
Senior Regulatory Affairs Specialist
77 Great Valley Parkway
Malvern, Pennsylvania 19355

December 18, 2015

Re: K153306

Trade/Device Name: Imbibe Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW, LXH
Dated: November 13, 2015
Received: November 16, 2015

Dear Ms. Lundy:

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,

Joshua C. Nipper -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

510(k) Number (if known)

K153306

Device Name

Imbibe Needle

Indications for Use (Describe)

The Imbibe Needle is for use in aspirating bone marrow or autologous blood by use of a syringe. The bone marrow or autologous blood may be combined with bone graft or bone void filler.

The Imbibe Needle is also for use in the placement of guidewires (e.g. k-wires) during orthopedic surgery.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

8. 510(k) Summary

510(k) Summary: Imbibe Needle	
Submitter:	Stryker Orthobiologics 77 Great Valley Parkway Malvern, PA 19355
Contact Person	Lynn Lundy, MBA, RAC Senior Regulatory Affairs Specialist Phone: 610-407-5256 Fax: 484-328-8803 Email: Lynn.Lundy@Stryker.com
Date Prepared	November 13, 2015
Trade Name	Imbibe Needle
Common Name	Gastroenterology-urology biopsy instrument
Proposed Class	Class II
Classification Names and Numbers	Instrument, Biopsy Orthopedic Manual Surgical Instrument 21 CFR §876.1075 21 CFR §888.4540
Product Code	KNW LXH
Predicate Devices	Stryker Imbibe Needle (K140414)
Device Description	The Imbibe Needle is a manually operated surgical instrument to assist with the aspiration of autologous blood or bone marrow and/or placing guidewires (e.g. k-wires) for orthopedic surgery. These guidewires may be used to place other hardware utilized in orthopedic procedures including pedicle screws.
Intended Use	The Imbibe Needle is for use in aspirating bone marrow or autologous blood by use of a syringe. The bone marrow or autologous blood may be combined with bone graft or bone void filler. The Imbibe Needle is also for use in the placement of guidewires (e.g. k-wires) during orthopedic surgery.
Summary of the Technological Characteristics	As established in this submission, the Imbibe Needle was shown to be substantially equivalent and has equivalent technological characteristics to its predicate device through comparison in areas including intended use, material composition, principles of operation and design.
Summary of the Performance Data	The new Imbibe Needle, subject of this Special 510(k), is the same device as the predicate. Previous testing of the predicate device (i.e. mechanical, cadaveric testing and biocompatibility) has demonstrated that Imbibe Needles is safe and effective for its intended use.
Conclusion	The proposed Imbibe Needle has identical indications, technological

510(k) Summary: Imbibe Needle	
	characteristics, and principles of operation as its predicate. The only difference between the new and the predicate device is the design of the package. A risk analysis was performed to demonstrate the Imbibe Needle with new packaging is substantially equivalent to the predicate device. The design verifications and validations performed as a result of the risk analysis and presented herein demonstrate the proposed device does not raise new questions of safety or effectiveness. Thus, the predicate device (K140414) and proposed device are considered substantially equivalent.