AUG 2 3 2011 K111741

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) - Submitter Information	
Name	Integra Burlington MA, Inc.
Address	22 Terry Avenue Burlington, MA 01803
Phone number	781-565-1227
Fax number	781-238-0645
Establishment Registration Number	1222895
Name of contact person	Kevin J. O'Connell
Date prepared	June 10, 2011
807.92(a)(2) - Name of device	
Trade or proprietary name	Integra™ CUSA NXT™ Bone Tips
Common or usual name	Ultrasonic Surgical Aspirator
Classification name	Instrument, Ultrasonic Surgical
Classification panel	General and Plastic Surgery
Regulation	Unclassified
Product Code(s)	LFL
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	Selector Ultrasonic Surgical Aspirator System with Bone Tip K071669 CUSA Selector NXT Ultrasonic Tissue Ablation System K081459 CUSA NXT Extended Length Tip K102258
807.92(a)(4) - Device description	
	The NXT Bone tips will attach to the Selector 24 kHz Neuro Short Handpiece (1523000M7) and will be controlled by the CUSA NXT console. Ultrasonic surgical aspirators facilitate the removal of cellular and other unwanted soft and hard (e.g. bone) tissue. These systems provide selective tissue disintegration with simultaneous irrigation and aspiration. The modification is intended to provide improved visualization due to the protruded abrasive cutting surface, concomitant with improved relief geometry to enable fine and precise shaving or cutting when fragmenting, emulsifying and aspirating hard tissue. There are two NXT Bone Tips. The Superior Forward Bone Tip has an abrasive surface that is oriented superiorly and distally at the distal end of the tip. The Superior Reverse Bone Tip has an abrasive surface

	that is oriented superiorly and proximally at the distal end of the tip. The NXT Bone Tips consist of a titanium tip with a titanium nitride coating, silicone flue and an ultem shroud. The NXT Bone Tips will be supplied sterile and are intended for single use.
807.92(a)(5) Intended use of the device	
Indications for use	The CUSA NXT Bone Tips are accessories to the CUSA NXT Ultrasonic Surgical Aspirator Systems that is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, Thoracic surgery, Laparoscopic surgery and Thoracoscopic surgery. The indications for use for the NXT system have not changed due to the addition of the NXT Bone Tips.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

Characteristic	CUSA NXT Bone Tips	Selector Ultrasonic Surgical Aspirator System with Bone Tip K071669	CUSA Selector NXT Ultrasonic Tissue Ablation System K081459	CUSA NXT Extended Length Tip K102258
Console used with tip	CUSA NXT	CUSA Selector	CUSA NXT	CUSA NXT CUSA Selector
Approximate Frequency of Operation	24 kHz	24 kHz	24 kHz	35 kHz
Max Stroke (inches)	0.0120	0.0120	0.0120	0.0069
Tips Delivered As	Sterile / Single Use	Sterile / Single Use	Sterile / Single Use	Non Sterile
Shroud	Uses a curved shroud, packaged with tip	Uses Shroud with handpiece	Uses Shroud with handpiece	Uses a straight shroud, packaged with tip
Vibration of Tip	Longitudinal	Longitudinal	Longitudinal	Longitudinal
Design of distal end	Protrusion with 10° inverse conical (Forward) Protrusion with 10° conical (Reverse)	Cylindrical shape with abrasive surface	Cylindrical shape with abrasive surface	Cylindrical shape with flat annulus
Pre-aspiration holes	Yes	No	No	Yes
Inner Diameter (inches)	0.078	0.078	0.078	0.062
Working Length (mm)	88	96	96	178
Bend Angle	20°	20°	20°	12°

Material				
Tip	Titanium 6AL4V Grade 5	Titanium 6AL4V Grade 5	Titanium 6AL4V Grade 5	Titanium 6AL4V Grade 5
Flue	Silicone	TPX	TPX	Silicone
Shroud	Ultem	Ultem	Ultem	Ultem

807.92(b)(1-2) NONCLINICAL TESTS SUBMITTED	
Test	Result
Electromechanical Test – measures frequency, stroke, lateral movement, and power	Passed frequency, stroke, lateral movement, and quiescent power acceptance criteria.
Lateral Load Test – applies a lateral load on the vibrating tip to evaluate robustness	Performance of the tips was not affected after the application of the lateral load.
Dry Flue Test – checks the effect of ultrasonically vibrating a surgical tip without the presence of irrigation	Performance of the tips was not affected when operated with no irrigation for the time specified.
Accelerated Stress Bone Cutting – tests the effect of bone cutting for extended periods of time	No breakage of the abrasive surface occurred.
Measurement of Thermal Rise During Ultrasonic Aspiration of Representative Tissue	Thermal rise in tissue field during tissue removal was found to be less than stated in the product specification.
Biocompatibility	Since the modified device uses materials that have the same chemical formulations, same manufacturing and same sterilization processes as in the predicate device, additional testing was not performed.

807.92(b)(3) CONCLUSIONS DRAWN FROM NON-CLINICAL DATA
Testing confirmed that the performance of the NXT Bone Tips meets the product specification of the modified tips, which are based on the predicate device. Therefore the modification resulted in a device that performs the same as the predicate device.

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

Integra Burlington MA, Inc.
% Mr. Kevin J. O'Connell
22 Terry Avenue
Burlington, Massachusetts 01803

AUG 23 2011

Re: K111741
Trade/Device Name: Integra™ CUSA NXT™ Bone Tips
Regulatory Class: Unclassified
Product Code: LFL
Dated: June 20, 2011
Received: June 21, 2011

Dear Mr. O'Connell:

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

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,

for 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 Statement

510(k) Number (if known): K111741

Device Name: Integra CUSA NXT Bone Tips

Indications for Use:

The CUSA NXT Bone Tips are accessories to the CUSA NXT Ultrasonic Surgical Aspirator System that is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, Thoracic surgery, Laparoscopic surgery and Thoracoscopic surgery.

PRESCRIPTION USE __X__ AND/OR Over-The-Counter Use__
(Part 21 CFR 801 Subpart D) (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 K111741