



Food and Drug Administration
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December 18, 2015

Integra Lifesciences Corp.
Jennifer Siegel
Regulatory, Quality and Clinical Associate
311 Enterprise Drive
Plainsboro, NJ 08536

Re: K150682
Trade/Device Name: CUSA® Excel+ Ultrasonic Surgical Aspirator System
Regulation Number: N/A
Regulation Name: Instrument, Ultrasonic Surgical
Regulatory Class: Unclassified
Product Code: LFL, LBK
Dated: October 20, 2015
Received: October 21, 2015

Dear Jennifer Siegel,

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" (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,


Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150682

Device Name

CUSA® Excel+ Ultrasonic Surgical Aspirator System

Indications for Use (Describe)

The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue in the following surgical specialties:

Neurosurgery, Orthopedic Surgery, Plastic and Reconstructive Surgery, and Thoracic Surgery and the following specific uses:

Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy

Urological Surgery – including removal of renal parenchyma during nephrectomy or partial nephrectomy

General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures

Laparoscopic Surgery – including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy

Gynecological Surgery – including removal of dysplastic genital or perianal epithelial tissue including vulvar and vaginal intraepithelial neoplasia, removal of condyloma, debulking of metastatic uterine, ovarian, fallopian tube or primary peritoneal carcinoma, and open or laparoscopic excision of tissue and adhesions associated with endometriosis.

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.

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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 LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone Number	609-936-5459
Establishment Registration Number	3003418325
Name of Contact Person	Jennifer Siegel
Date Prepared	02/18/2014
807.92(a)(2) – Name of device	
Trade or Propriety Name	CUSA® Excel+ Ultrasonic Surgical Aspirator System
Common or Usual Name	Ultrasonic Surgical Aspirator
Classification Name	Instrument, Ultrasonic Surgical
Classification Panel	General and Plastic Surgery
Regulation	Class II unclassified
Product Code(s)	LFL, LBK
807.92(a)(3) – Legally marketed device(s) to which equivalence is claimed	
CUSA® Excel Plus Ultrasonic Surgical Aspirator; K141668	
Reference Devices: CUSA® 200C, 200T, 200M, 200H Ultrasonic Aspirator; K894600 CUSA® 200C, 200T Ultrasonic Aspirator; K931902	
807.92(a)(4) – Device description	
<p>The CUSA® Excel+ Ultrasonic Surgical Aspirator System (CUSA) is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective dissection of target tissue while preserving vessels, ducts and other delicate structures. The CUSA Excel+ System consists of a console which provides control and power functions, two surgical hand pieces which provide ultrasonic mechanical energy (23kHz and 36kHz), titanium hand piece tips (variety of models), flexible irrigation flue, and a suction/irrigation system (manifold tubing and cooling water canister). The CUSA Excel+ system accommodates most commercially available suction canisters. A two-pedal footswitch is provided with the console.</p>	

807.92(a)(5) – Intended use of the device

<p>Indications for Use</p>	<p>The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue in the following surgical specialties:</p> <p>Neurosurgery, Orthopedic Surgery, Plastic and Reconstructive Surgery, and Thoracic Surgery and the following specific uses:</p> <p>Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy</p> <p>Urological Surgery – including removal of renal parenchyma during nephrectomy or partial nephrectomy</p> <p>General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures</p> <p>Laparoscopic Surgery – including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy</p> <p><i>Gynecological Surgery – including removal of dysplastic genital or perianal epithelial tissue including vulvar and vaginal intraepithelial neoplasia, removal of condyloma, debulking of metastatic uterine, ovarian, fallopian tube or primary peritoneal carcinoma, and open or laparoscopic excision of tissue and adhesions associated with endometriosis</i></p>
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	<p>This 510(k) adds specific indications to the already cleared general indications for the CUSA Excel+. The addition of these new indications does not change the intended use of the CUSA Excel+ as these indications do not alter the principles of operations (ultrasonic ablation) for this device.</p>
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807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

The technological characteristic of the device are the same compared to the predicate device.

807.92(b)(1-2) – Nonclinical and clinical tests submitted

Integra performed a bench study to assess the impact and significance of spray patterns. A series of randomized experiments covering different settings were performed. Irrigation spray was imaged and plotted for different operating settings of the CUSA system. The results showed spray can be controlled to levels very close to zero at amplitude and aspiration settings seen during typical use. Low amplitude and high aspiration yielded reduced spray.

The clinical evidence used to support the revision to the indications for use is provided from peer-reviewed clinical literature. An analysis of peer-reviewed articles on the use of CUSA presents clinical evidence to support the indications of CUSA in Gynecological Surgery. The clinical literature describes the use of CUSA for these indications in over 500 patients in 34 articles published between 1988 and 2014. Specifically, in the literature, CUSA was used to treat 230 patients with dysplasia, 101 patients with condyloma, 164 patients requiring debulking procedures, and 15 patients with endometriosis. In dysplasia cases, CUSA produced excellent cosmetic results with limited scarring and, compared to topical treatments, CUSA effectively reduced recurrence rates. Specifically, VAIN (Vaginal Intraepithelial Neoplasia) is inherently a problematic disease to treat due to its anatomical location. Use of CUSA successfully overcame this difficulty with VAIN while resulting in minimal bleeding.

Likewise, in condyloma cases, CUSA was successful in achieving desired treatment outcomes. As in the case of VAIN and VIN (Vulvar Intraepithelial Neoplasia), CUSA allowed for removal of epithelial lesions with fast healing, minimal patient discomfort, and improved cosmetic results in condyloma-related procedures. In the clinical literature, use of CUSA also did not result in any postoperative complications or scarring.

In debulking cases, CUSA allowed for dissection of tumor masses that could not be resected safely by standard techniques or were located in areas that were considered unresectable. Many articles demonstrated the safe and effective use of CUSA in debulking ovarian cancer, as well as metastases from endometrial cancer, tubal adenocarcinoma, and peritoneal tumors. In these cases, CUSA significantly reduced or eliminated residual disease with minimal complications while not requiring the resection of normal structures. One article noted risk of DIC (Disseminated Intravascular Coagulation), however, no other studies found such a risk of DIC in a CUSA population of over 500 patients.

In cases where endometrial tissue was removed, CUSA effectively removed the endometrial tissue while preserving vessels and nerves.

It should be noted that one case study for the treatment of vulvar carcinoma, which is outside the scope of these expanded indications, suggests a risk of dissemination by CUSA. However, the author states in the conclusion of the study that “it is impossible to assess whether the early locoregional tumor recurrence in this patient was related to the use of CUSA or was due to embolization of the micrometastases before surgery.” CUSA offers significant benefits in Gynecological Surgery, such as decreased complications, improved cosmetic effect, and the ability to reach difficult locations that impact patient survival. CUSA is able to remove lesions while not damaging surrounding tissue. Therefore, patients are able to have a same day discharge for many of these critical procedures.

807.92(b)(3) – Conclusions drawn from non-clinical and clinical data

The information from the nonclinical testing and the peer reviewed clinical literature supports the proposed changes from general to specific indications in gynecologic surgery.