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

November 6, 2014

Integra LifeSciences Corporation
Ms. Janet C. Kay
Director, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K141668
Trade/Device Name: CUSA® Excel+ Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL
Dated: October 8, 2014
Received: October 10, 2014

Dear Ms. Kay:

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

510(k) Number (if known): K141668

Device Name:

CUSA® Excel+ Ultrasonic Surgical Aspirator System

Indications For Use:

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

Neurosurgery, Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological 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

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Prescription Use ___X___ **AND/OR** **Over-The Counter Use_____**

(Per 21 CFR 801 Subpart D) **(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 (ODE)

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	781-565-1347
Fax Number	781-238-0645
Establishment Registration Number	3003418325
Name of Contact Person	Janet C. Kay
Date Prepared	September 22, 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
807.92(a)(3) – Legally marketed device(s) to which equivalence is claimed	
CUSA Excel Ultrasonic Surgical Aspirator System K981262 CUSA Excel Ultrasonic Surgical Aspirator System with Bone Tip K051947	
807.92(a)(4) – Device description	

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.

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

Indications for Use	The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in: Neurosurgery, Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological 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

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

No nonclinical testing was required as the device itself was not modified.

The clinical evidence used to support the change to the indications for use for Gastrointestinal (GI) and Affiliated Organ, Urologic, General, and Laparoscopic surgeries are peer reviewed journal articles:

Gastrointestinal and Affiliated Organ Surgery –
The largest body of data found was for GI and affiliated organ surgeries. Thirty-four articles reported on approximately 2,500 cases, including open hepatectomy and laparoscopic-assisted liver resection. Overall, the literature demonstrated that CUSA can be safely used in laparoscopic and open liver surgeries. The laparoscopic technique using CUSA has been shown to decrease morbidity, shorten hospital stay, improve cosmesis, and decrease blood loss. The literature showed CUSA to be safe and effective in liver surgery for pediatric, adult, and elderly patients and it has also been proven acceptable in both open and laparoscopic procedures.

Urologic Surgery –
Six articles report on the use of the CUSA system in renal surgical cases. These cases included resections performed for renal lithiasis and renal tumor removal and formation of a nipple valve during construction of a continent ileal urinary reservoir. A total of 8 urologic resection cases and 71 cases of nipple valve formation during construction of a continent ileal urinary reservoir were reported. No adverse events were reported with the use of the CUSA in these cases. The articles found that using CUSA for renal resection allows the surgeon to selectively aspirate certain tissues, including parenchyma, while leaving blood vessels and collecting systems intact. The literature reported that using CUSA resulted in increased visibility for the surgeons, reduced operating time, and a reduced volume of blood loss due to its selectivity.

General Surgery –
References are provided on the use of CUSA for the resection of carcinoma of the tongue in small numbers (10 patients) and treatment of using CUSA in papillary cystic and solid tumor of the pancreas (PCSTP) in children (5 cases). Although these case reports involve small numbers of patients no significant issues of safety or effectiveness are identified for the use of

CUSA device in these specific indications.

Laparoscopic Surgery –
Eight articles and two abstracts reveal that CUSA has been successfully used in laparoscopic appendectomies, laparoscopic colon resections, laparoscopic cholecystectomies, laparoscopic partial gastrectomies, laparoscopic transhiatal esophagectomy, laparoscopic ablation of endometriosis, and laparoscopic hepatectomies. One hundred thirty-one laparoscopic cholecystectomies, nine laparoscopic appendectomies, three laparoscopic colon resections, and two laparoscopic partial gastrectomies were performed using CUSA. The only complication observed in these cases was a thermal pinhole burn leading to bile leakage in one case of laparoscopic cholecystectomy. The articles for these cases reported that the advantage of using CUSA for these procedures included the ability of the system to dissect tissues while preserving the main structures. Six cases of laparoscopic esophagectomy were also completed using CUSA. The authors observed that using CUSA allowed for the isolation of vessels and periesophageal lymph nodes during the procedure and that transhiatal esophagectomies were performed successfully in all patients without massive bleeding. Over 150 laparoscopic hepatectomy procedures were performed using the CUSA system. Most of the articles presented concluded that use of CUSA led to successful surgical outcomes and reduced blood loss. The laparoscopic surgery articles presented in the literature review indicate that ultrasonic aspiration is a safe technology in a number of laparoscopic procedures. It may have advantages including less blood loss and preservation of main structures, including vessels and ducts.

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

The changes from general to specific indications for use are supported by the information provided including previously cleared 510ks and peer reviewed clinical literature.