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

September 28, 2017

Integra LifeSciences Corporation
Alexandra Wells
Regulatory and Quality Associate
311 Enterprise Drive
Plainsboro, NJ 08536

Re: K172595
Trade/Device Name: CUSA® Excel+ Ultrasonic Surgical Aspirator System
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LFL, LBK
Dated: August 28, 2017
Received: August 29, 2017

Dear Alexandra Wells:

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 (DICE) 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 (DICE) 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172595

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.

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	1-609-275-0500
Fax Number	1-609-275-5363
Establishment Registration Number	9004007
Name of Contact Person	Alexandra Wells
Contact Email	alexandra.wells@integralife.com
Date Prepared	08/24/2017
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	None
Classification Panel	General & Plastic Surgery
Regulation	Unclassified
Product Code(s)	LFL, LBK
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
Trade or Propriety Name	CUSA® Excel+ Ultrasonic Surgical Aspirator System
510(k) Number	K150682
Product Code	LFL, LBK
Manufacturer	Integra LifeSciences Corporation

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), 18 titanium hand piece tips (variety of models), a flexible irrigation flue, and a suction/irrigation system (manifold tubing and cooling water canister). The CUSA Excel+ system accommodates most commercially available suction canisters, and specimen traps (optional). A two-pedal footswitch is provided with the console. The CUSA Excel+ System may also be used with an external CUSA Electrosurgical Module (CEM), which provides optional electrosurgical capability.	
807.92(a)(5) – Intended use of the device	
Indications for Use	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 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
Comparison to Predicate Device	The change included in this submission is an update to the CUSA Excel+ labeling to remove the following debulking contraindication:

	Contraindication: Use of the device for tumor debulking should be limited to patients where the benefits of debulking are believed to outweigh the risks of further dissemination of malignant cells. There is no change to the indications for use or intended use of the device when compared to the predicate. Additionally, the labeling change does not affect the materials of composition, manufacturing and sterilization process, or the fundamental scientific technology of the device. The removal of the subject contraindication does not affect the risk profile of the device as the risk of dissemination in the context of uterine fibroids is already addressed under an existing uterine fibroids contraindication. As such, the change does not affect the safety or effectiveness of the device.
807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate	
There are no changes to the technological characteristics of the CUSA Excel+ when compared to the predicate.	
807.92(b)(1-2) – Nonclinical and clinical tests referenced	
Integra performed a bench study to assess the impact and significance of misting, which was previously submitted as part of K150682. 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, which is addressed in the labeling. Integra also completed a risk-benefit analysis in order to assess the potential risk associated	

with the dissemination of malignant cells leading to an unexpected reoccurrence or upstaging of cancer. This analysis included a risk assessment, clinical literature review, clinical perspective and post-market surveillance information relating to the use of the CUSA Excel+. The review and analysis of this information did not identify a causal relationship between CUSA use and risks associated with dissemination of malignant cells. Furthermore, it was concluded that the benefits of using CUSA for the removal of unwanted tissue in surgery outweighs the risk of disseminating malignant cells.

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

The information from the nonclinical testing, peer reviewed clinical literature, post-market surveillance and risk-benefit analysis concluded that the benefits of using CUSA for the removal of unwanted tissue in surgery outweighs the risks of disseminating malignant cells. It was also concluded that the debulking contraindication does not improve the risk-benefit profile of the device; therefore, the removal of the debulking contraindication would not affect the safety and effectiveness of the device nor alter its performance or function when compared to the predicate. Review and analysis of this information supports the changes in the CUSA Excel+ labeling and the substantial equivalence of the device described in this submission when compared to the predicate.