DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 14, 2016

Integra LifeSciences Corporation
Mr. Resham Ramsay
Quality, Clinical, and Regulatory Associate
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K161882
Trade/Device Name: CUSA Clarity Ultrasonic Surgical Aspirator System
Regulation Name: Instrument, Ultrasonic Surgical
Regulatory Class: Unclassified
Product Code: LFL, LBK
Dated: September 13, 2016
Received: September 14, 2016

Dear Mr. Resham Ramsay:

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,

Jennifer R. Stevenson -A

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161882

Device Name
CUSA Clarity Ultrasonic Surgical Aspirator System

Indications for Use *(Describe)*
The CUSA® Clarity Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable.

The CUSA Clarity 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 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

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	609-275-0500
Fax Number	609-275-9445
Establishment Registration Number	9004007
Name of Contact Person	Resham Ramsay
Date Prepared	July 8, 2016
807.92(a)(2) – Name of device	
Trade or Propriety Name	CUSA® Clarity Ultrasonic Surgical Aspirator System
Common or Usual Name	Ultrasonic Surgical Aspirator
Classification Name	Instrument, Ultrasonic Surgical
Classification Panel	General and Plastic Surgery
Regulation	Unclassified
Product Code(s)	LFL, LBK
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
CUSA® Excel+ Ultrasonic Surgical Aspirator System K141668 CUSA® NXT Ultrasonic Tissue Ablation System K081459	

807.92(a)(4) - Device description

The CUSA® Clarity Ultrasonic Surgical Aspirator System is the newest device to be added to the Integra Lifesciences Corporation family of tissue ablation products. There are two (2) systems currently marketed in the United States: CUSA® Excel+ Ultrasonic Surgical Aspirator System and CUSA® NXT Ultrasonic Tissue Ablation System These two systems as well as all predecessor devices share(d) the same principle of operation. All CUSA systems are surgical aspirators which use ultrasonics and cavitation to fragment and emulsify tissue, and aspiration at the end of the surgical tip to remove unwanted tissue. Each model has unique features and attributes that may not be found in the others. Like the predicate devices, CUSA Clarity is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies, and removes unwanted tissue. It allows for the selective dissection of target tissue while preserving vessels, ducts, and other delicate structures. The CUSA Clarity consists of a console that provides power and control of the ultrasonic, aspiration and irrigation functions, a surgical handpiece that provides ultrasonic mechanical energy, a footswitch to allow user control over the ultrasonics, a titanium surgical tip, irrigation flue, and a suction/irrigation system (manifold tubing and vacuum canister). The CUSA Clarity system, including all accessories and components, will be labeled MR Unsafe.

807.92(a)(5) – Intended use of the device	
Indications for Use	The CUSA® Clarity Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable. The CUSA Clarity 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 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 CUSA Clarity has the same technological characteristics compared to the predicate devices. The main purpose of the CUSA Clarity at this time is to update the CUSA platform while maintaining the same underlying technology and intended use of previous CUSA devices, consolidate some of the best features from the two predicate devices into one system, and to add minor design improvements that generally focus on improving ease-of-use. Thus, the majority of the features and technology of the CUSA Clarity are not new for a CUSA device and benefit longstanding safety and/or efficacy.

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

A suite of performance tests was executed to show substantial equivalence with the predicate devices. Testing included, but was not limited to:

- Sterilization, cleaning, shipping and stability testing per FDA Guidance documents and recognized standards
- Biocompatibility testing per FDA Guidance documents and recognized standards
- Software testing per FDA Guidance document and recognized standards
- EMC and Electrical Safety testing per FDA recognized standards
- Bench testing per various internal protocols

Testing was determined successful for all 50 protocols and supports the conclusion that all design inputs have been met. Integra LifeSciences therefore believes verification testing results for the CUSA Clarity support a determination of substantial equivalence when compared with the predicate devices.

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

The results of the non-clinical testing indicate that the intended use of the device, fundamental scientific technology, and performance of the CUSA Clarity are substantially equivalent to the predicate devices.