December 7, 2018

Integra LifeSciences Corporation
MaryBeth Carson
Regulatory, Quality and Operations Associate
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K182809
Trade/Device Name: CUSA Clarity Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL, LBK
Dated: October 2, 2018
Received: October 3, 2018

Dear Marybeth Carson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
To Be Determined K182809

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 and hard (e.g. bone) 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 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

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, New Jersey 08536
Telephone Number	609-275-0500
Establishment Registration Number	9004007
Contact Person	MaryBeth Carson
Date Summary Prepared	October 2, 2018
807.92(a)(2)- Name of Device	
Trade or Proprietary 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
Device Class	Unclassified
Product Code(s)	LFL, LBK
807.92(a)(3)- Legally Marketed Devices to Which Submitter Claims Equivalence	
CUSA® Clarity Ultrasonic Surgical Aspirator System K161882 CUSA® Excel+ Ultrasonic Surgical Aspirator System K141668	
807.92(a)(4)- Device Description	
The CUSA® Clarity Ultrasonic Surgical Aspirator System was originally cleared October 14, 2016 (K161882). The purpose of this submission is to obtain FDA clearance for expanding the current CUSA Clarity indication for use statement to add a hard tissue indication (bone) and to add a 23 kHz handpiece and related accessories for use with the previously cleared CUSA Clarity system. The submission includes a bone tip that facilitates the removal of hard tissue, and additional tips intended for the removal of soft tissue. The CUSA Clarity system shares the same intended use and principle of operation as previous CUSA systems. All CUSA systems are surgical aspirators that use ultrasonics and cavitation,	

in combination with irrigation and aspiration, to fragment, emulsify and remove 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, two surgical handpieces that provides ultrasonic mechanical energy (23 kHz and 36 kHz), a footswitch to allow user control over the ultrasonics, titanium surgical tips (variety of models), irrigation flues, suction/irrigation system (manifold tubing and vacuum canister) and accessories used for assembly/disassembly and reprocessing. The CUSA Clarity system, including the 23 kHz components that are the subject of this submission, will be labelled MR Unsafe.

807.92(a)(5)- Intended Use of 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 and hard (e.g. bone) 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 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 Technological Characteristics Compared to the Predicate

The CUSA Clarity system with the 23 kHz components has the same technological characteristics compared to the predicate devices. All CUSA devices utilize ultrasonic mechanical action to fragment unwanted tissue while simultaneously providing irrigation and aspiration. The purpose of this submission is to add in 23 kHz components to be used with the previously cleared CUSA Clarity system and expand the current CUSA Clarity indications. The result is a CUSA Clarity system that will match the functionality and indications offered by the CUSA Excel+, which has a hard tissue indication and is cleared with both 23 kHz and 36 kHz handpieces. The same underlying technology and intended use of previous CUSA devices is maintained with the addition of the CUSA Clarity 23 kHz components, as the functionality is carried over from the predicate devices with 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)- Non-clinical and clinical tests submitted

Performance testing was executed to demonstrate 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
- Electrical Safety and EMC testing per FDA recognized standards
- Bench testing to verify system requirements, including those listed below
    - Tissue Fragmentation Rate
    - Handpiece and Tip Life
    - Torque functionality during assembly

- Operating frequency
- Functionality within specification during environmental variations
- Aspiration and Irrigation flow

Testing was determined successful for all 42 protocols within the 5 testing categories above and supports the conclusion that all product specifications and design inputs have been met. Integra LifeSciences therefore believes verification testing results for the CUSA Clarity system with the 23 kHz components support a determination of substantial equivalence when compared with the predicate devices.

No clinical studies were performed or required as all conducted performance tests appropriately support a determination of substantial equivalence compared with the predicate devices.

807.92(b)(3)- Conclusions drawn from the nonclinical and clinical tests

The results of the non-clinical testing indicate that the intended use of the device, fundamental scientific technology and performance of the CUSA Clarity system with 23 kHz components are substantially equivalent to the predicate devices.