**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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

November 12, 2015

**OVERNIGHT DELIVERY**
**SIGNATURE REQUIRED**

Alicia Nakonetschny
President and CEO
Custom Ultrasonics, Inc.
144 Railroad Dr.
Ivyland, Pennsylvania 18974

Re: Consent Decree of Permanent Injunction entered in *United States v. Custom Ultrasonics, Inc.*, Civil Action No. 06-5267 (E.D. Pa.)

Dear Ms. Nakonetschny:

As you are aware, the United States Food and Drug Administration (FDA or the agency) has been evaluating a potential postmarket safety concern relating to Custom Ultrasonics, Inc.'s automated endoscope reprocessors (AERs), namely, the System 83 Plus, System 83 Plus 2, and System 83 Plus 9 (collectively, System 83 Plus). FDA's evaluation followed reports of infections at several hospitals associated with the use of reprocessed duodenoscopes following Endoscopic Retrograde Cholangiopancreatography (ERCP). Several health care facilities with confirmed or possible duodenoscope-associated infections used the System 83 Plus for high-level disinfection of duodenoscopes after ERCP procedures.

As part of the agency's evaluation, on March 5, 2015, FDA's Center for Devices and Radiological Health (CDRH) requested information from you, including reprocessing validation for the System 83 Plus, complaint handling processes, and complaint and Medical Device Reporting (MDR) summaries. Additionally, between April 9 and 24, 2015, FDA conducted an inspection of the Custom Ultrasonics' facility located at 144 Railroad Drive, Ivyland, Pennsylvania, to assess compliance with Quality System and MDR requirements. In recent months, CDRH has reviewed Custom Ultrasonics' revised validation protocols and testing for the System 83 Plus.

These activities follow Custom Ultrasonics' lengthy regulatory history. On January 26, 2007, Custom Ultrasonics was enjoined from manufacturing, packing, labeling, and distributing devices under a Consent Decree of Permanent Injunction (Consent Decree) entered in the above-referenced action. On May 8, 2007, following a facility inspection, FDA permitted Custom Ultrasonics to resume operations on a limited basis, only as to the System 83 Plus. Subsequently, on September 5, 2012, FDA ordered Custom Ultrasonics to cease operations and recall all System 83 Plus devices due to Custom Ultrasonics' reoccurring violations of the Federal Food, Drug, and Cosmetic Act (Act), applicable regulations, and the Consent Decree. On June 7, 2013, after documenting additional violations during a facility inspection, FDA further ordered Custom Ultrasonics to, among other actions, continue to cease operations, recall

System 83 Plus devices in accordance with a recall proposal, and pay liquidated damages assessed under the Consent Decree.

Most recently, FDA received your request to resume manufacturing and distributing the System 83 Plus, dated March 2, 2015, and your communication on the subject dated October 30, 2015. By letter dated April 14, 2015, FDA agreed to reconsider your request to resume operations after evaluating the potential postmarket safety concerns relating to the System 83 Plus.

FDA has completed its evaluation of potential postmarket safety concerns related to the System 83 Plus. The agency has reviewed your responses to the March 2015 information request; the evidence collected during the April 2015 inspection; your written responses to the inspectional observations submitted to FDA on various dates from May 8, 2015, to October 15, 2015; and the reprocessing validation information you have provided to FDA over the last several months, most recently on October 19 and 30, 2015. Based on its review, FDA has concluded that Custom Ultrasonics has failed to comply with the Act, applicable regulations, and paragraphs 4 and 5 of the Consent Decree. In light of the violations set out in this letter, FDA denies your request to resume operations and is invoking paragraph 5 of the Consent Decree to order you to take additional corrective action, as described in Section III below. Until you receive written notification from FDA that you appear to be in compliance with the Act, its implementing regulations, and the Consent Decree, you are not permitted to resume operations.

## I. Violations

Custom Ultrasonics has violated the Quality System regulation at 21 C.F.R. Part 820, by failing to establish and maintain adequate procedures for validating the device design of the System 83 Plus, as required by 21 C.F.R. § 820.30(g), to ensure that the devices conform to defined user needs and intended uses. For example, Custom Ultrasonics has failed to:

- Validate the retention performance of the water filtration assembly over various operating conditions to ensure that variations in water quality do not have an adverse effect on the operation of the System 83 Plus. The device's water filtration assembly must effectively remove particulates, including microorganisms, so intake feed water is acceptable for subsequent washing and rinsing of endoscopes during reprocessing. Adequate filtration is necessary to prevent the release of waterborne or residual pathogens into the System 83 Plus that may contaminate endoscopes after the reprocessing disinfection stage and to ensure that endoscopes will not transmit residual pathogens that may pose health risks to patients.

- Validate the pre-filters used in the System 83 Plus which guard against large particulates and debris. MDRs submitted to FDA reported System 83 Plus filter occlusions, which can impede the fluid flow and pressure during reprocessing and reduce the required pressure flows needed to ensure adequate rinsing and disinfection. There is no assurance that the System 83 Plus can maintain the reprocessing parameters for adequately rinsing and disinfecting the endoscopes, which may result in the transmission of residual pathogens to patients.

- Validate the compatibility of the System 83 Plus with the HLDs (High Level Disinfectants) used by health care facilities in reprocessing endoscopes, as claimed in the

device's operations manual. Lack of validated performance requirements, such as temperature, exposure time, and compatibility for the various HLDs can result in inadequate disinfection of the endoscopes, leading to increased risk of transmission of residual pathogens to patients.

- Validate the reprocessing of complex endoscopes, including duodenoscopes with a closed elevator (lifter) channel, even after learning that those endoscopes are exceptionally difficult to successfully reprocess. Inadequate reprocessing of such complex endoscopes can result in devices with residual debris and inadequate disinfection. Inadequately disinfected devices may transmit residual pathogens and put patients at risk of infection.

Custom Ultrasonics' continued failure to validate the System 83 Plus device design impairs its ability to adequately service System 83 Plus devices presently on the market to consistently and reliably achieve high-level disinfection as intended. *See* 21 C.F.R. § 820.200 (Quality System regulation postproduction servicing requirements).

Custom Ultrasonics has also failed or refused to furnish material or information with respect to the System 83 Plus, specifically reports of corrections, as required by the Act, 21 U.S.C. § 360i, and 21 C.F.R. Part 806. On December 31, 2014, Custom Ultrasonics issued Technical Bulletin (TB-007), "Updated Preventative Maintenance Requirements & Notification of Ultrasonic Alert System Enhancement for the System 83 Plus (Washer/Disinfector)," and on January 16, 2015, Technical Bulletin TB-009, "Ultrasonics Failure Alert System (UFAS) Enhancement," to address ultrasonication failures associated with the System 83 Plus devices. Custom Ultrasonics failed to submit written reports to FDA of these corrections, as required by 21 U.S.C. § 360i and 21 C.F.R. § 806.10, in violation of 21 U.S.C. § 331(e).

## II. Other Nonconformances

FDA also notes that Custom Ultrasonics has deviated from the MDR requirements at 21 C.F.R. Part 803. For example, Custom Ultrasonics failed to report to FDA no later than 30 calendar days after the day that it received or otherwise became aware of information, from any source, that reasonably suggests that the System 83 Plus malfunctioned and this device would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 C.F.R. § 803.50(a)(2). Specifically, you failed to report to FDA within the required 30-calendar-day timeframe MDR 2523209-2014-00005 for Complaint 140022 (which references a System 83 Plus malfunction involving failed voltage regulators). Additionally, you have failed to develop, maintain, and implement adequate written MDR procedures as required by 21 C.F.R. § 803.17. Your firm's MDR procedure titled "Custom Ultrasonics, Inc., Medical Device Reporting (MDR)," 8P10-W01, lacks detail sufficient to allow a person to evaluate a complaint to determine whether the complaint meets the criteria for reporting under 21 C.F.R. § 803.50(a). This deficiency could lead to incorrect reportability decisions when evaluating complaints for the System 83 Plus.

## III. Order of Corrective Action

For the reasons set forth in Section I above, FDA has determined that Custom Ultrasonics has failed to comply with the Act, applicable regulations, and the Consent Decree. Therefore, in accordance with paragraph 5 of the Consent Decree, **FDA hereby orders Custom Ultrasonics to recall all System 83 Plus devices** released or distributed by Custom Ultrasonics or under the custody and control of your agents, distributors, customers, or consumers, at Custom Ultrasonics' expense. FDA deems this corrective action necessary to protect the public health. *See* Consent Decree ¶ 5.

In accordance with paragraph 5 of the Consent Decree, Custom Ultrasonics must immediately implement this order. Within seven (7) business days after receiving this order, Custom Ultrasonics must submit to FDA, in writing, a proposal to recall all System 83 Plus devices. The written recall proposal must address user facilities' ability to transition from the System 83 Plus as soon as possible. Additionally, Custom Ultrasonics must submit monthly reports to FDA, beginning no later than December 15, 2015, detailing the status of its servicing operations and expected timeframes for its discontinuation of servicing as user facilities transition from the System 83 Plus.

Paragraph 6 of the Consent Decree authorizes FDA to assess liquidated damages for Custom Ultrasonics' failure to comply with any provision of the Consent Decree, including the requirement to immediately implement this order as described above. FDA is not assessing liquidated damages for the violations described in this letter at this time but reserves the right to assess such damages in the future. Please also be advised that FDA may seek any and all appropriate legal and equitable remedies from the Court, including, but not limited to, civil or criminal contempt.

## IV. Conclusion

This order supplements and in no way alters any previously issued FDA order under the Consent Decree, and it shall be implemented consistent, and in conjunction, with all such orders, including those dated September 5, 2012, and June 7, 2013. As set forth in paragraph 11 of the

Consent Decree, please submit all communications regarding this matter to FDA in writing at: District Director, Philadelphia District Office, U.S. Food and Drug Administration, U.S. Customhouse Room 900, 200 Chestnut Street, Philadelphia, PA 19106.

Sincerely,

Anne E. Johnson -S

Digitally signed by Anne E. Johnson -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300059868, cn=Anne E. Johnson -S
Date: 2015.11.12 14:54:23 -05'00'

Anne E. Johnson
Acting Director
Philadelphia District
Office of Regulatory Affairs

CAPT Sean Boyd
Acting Director of Compliance
Office of Compliance
Center for Devices and Radiological Health

cc:

Stephen D. Terman
Olsson Frank Weeda Terman Matz PC
600 New Hampshire Avenue, N.W.
Suite 500
Washington, D.C. 20037

Melissa J. Mendoza, Associate Chief Counsel for Enforcement, FDA