



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

January 29, 2016

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:

On November 12, 2015, pursuant to the Consent Decree of Permanent Injunction (Consent Decree) entered in the above-referenced action, FDA ordered Custom Ultrasonics, Inc. (Custom Ultrasonics or the firm) to recall, at its expense, all of its automated endoscope reprocessors (AERs), namely, all System 83 Plus, System 83 Plus 2, and System 83 Plus 9 AERs (collectively, System 83 Plus) released or distributed by Custom Ultrasonics or under the custody and control of its agents, distributors, customers, or consumers (hereinafter, "Recall Order"). On November 24, 2015, Custom Ultrasonics provided to FDA a proposal to recall the System 83 Plus. The recall proposal is inadequate, in large part because it offers to correct System 83 Plus devices presently on the market rather than to remove those devices from use as directed by the Recall Order: "[Custom Ultrasonics'] written recall proposal must address user facilities' ability to transition from the System 83 Plus as soon as possible."

On December 11, 2015, after FDA granted Custom Ultrasonics request for a meeting, FDA representatives met with you and other firm representatives to discuss the System 83 Plus recall strategy. During the meeting, FDA explained that your proposal to correct the devices was unacceptable and emphasized that Custom Ultrasonics must remove from the market, rather than attempt to correct, all System 83 Plus devices as soon as possible. During the meeting, you committed to provide to FDA a written recall strategy for removing the System 83 Plus from the market, which you have yet to submit to FDA. FDA's Center for Devices and Radiological Health (CDRH) agreed to further explain the reasons your corrective actions to date fail to address the violations set forth in the Recall Order. That evaluation of your corrective actions is set forth below in section II.

As explained below, FDA hereby reaffirms the Recall Order and orders Custom Ultrasonics to immediately recall all System 83 Plus devices by removing those devices from use.

I. Response to Custom Ultrasonics' Recall Proposal

Your recall proposal fails to provide a strategy for removing System 83 Plus devices presently on the market. Instead, you offer to correct System 83 devices in place. As further described below, the corrections you propose would require you to obtain new FDA clearance for the System 83 Plus pursuant to section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 360(k). FDA regulations require you to submit a new premarket notification to FDA for a change or modification to a device that could significantly affect the safety or effectiveness of the device in commercial distribution. See 21 C.F.R. § 807.81(a)(3); see also FDA Guidance: Deciding when to submit a 510(k) for a Change to an Existing Device (k97-1) (Jan. 10, 1997), available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm>. The changes or modifications you have proposed require new FDA clearance for the System 83 Plus through the 510(k) submission process because they could significantly affect the safety or effectiveness of the device, and FDA understands that you have initiated that process by requesting feedback from CDRH through the Pre-Submission Program. In accordance with FDA's Recall Order and paragraph 5 of the Consent Decree, however, Custom Ultrasonics must immediately recall all System 83 Plus devices presently on the market by removing those devices from use.

FDA has reviewed each element of your recall proposal and responds as follows:

1. You propose to notify each user that the System 83 Plus is b(4) CCI [REDACTED]

The proposed b(4) CCI [REDACTED] represent a change or modification to the System 83 Plus, which you have yet to validate. Such a change or modification could significantly affect the safety or effectiveness of the System 83 Plus, and requires you to obtain a new 510(k). See 21 C.F.R. § 807.81(a)(3). FDA acknowledges that Custom Ultrasonics has tested the System 83 Plus with three Pentax duodenoscopes. That validation testing, however, is incomplete and fails to demonstrate how the System 83 Plus performs with other endoscopes or to support use of the System 83 Plus with other duodenoscopes that are not contraindicated.

2. You propose to notify each System 83 Plus user by way of a b(4) CCI [REDACTED] b(4) CCI [REDACTED] of:
 - a. The critical requirement to perform water filter "Daily Pre-Checks" for Pressure Differential to assess filter integrity and to STOP using the System 83 Plus if the 25 per square inch (psi) differential is exceeded in accordance with the Operator's Manual; and
 - b. The critical requirement that the USER MUST replace water filters and components for the System 83 Plus with Custom Ultrasonics original equipment manufacturer (OEM) parts.

You further propose to provide users b(4) CCI [REDACTED] to the System 83 Plus that is clearly visible to the user and warns the user to check daily the 25 psi maximum water filter pressure differential requirement and to use only Custom

Ultrasonics OEM parts. You also offer to provide to users an **b(4) CCI** on the Custom Ultrasonics website to demonstrate how to conduct daily pressure differential checks.

These proposals represent changes or modifications in the device that could significantly affect the safety or effectiveness of the System 83 Plus, specifically pertaining to the use of its water filter, and such changes or modifications require a new 510(k). See 21 C.F.R. § 807.81(a)(3). Moreover, adding additional instructions as a correction to a process that has not been validated provides 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.

3. Custom Ultrasonics proposes to notify each System 83 Plus user by way of a **b(4) CCI** of the requirement that, prior to each washing cycle, the user must check the minimum effective concentration (MEC) of the high level disinfectant according to the disinfectant manufacturer's instructions and the Custom Ultrasonics Operator's Manual. You also propose to amend the System 83 Plus **b(4) CCI** to reflect that only specified **b(4) CCI** should be used until further validation of other commonly used HLD's are provided to the agency.

These proposals are inadequate. Limiting the System 83 Plus's use to one type of high level disinfectant represents a change or modification in the device that could significantly affect the safety or effectiveness of the System 83 Plus, and such a change or modification requires a new 510(k). See 21 C.F.R. § 807.81(a)(3). Moreover, adding **b(4) CCI** as a correction to a process that has not been validated provides 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.

4. You propose to notify each user of the System 83 Plus by way of a **b(4) CCI** **b(4) CCI** of the requirement to replace the 250 micron inline disc filters **b(4) CCI**. You further propose to include an **b(4) CCI**

These proposals are inadequate. Adding **b(4) CCI** of the inline filters increases the frequency for replacing the filters and represents a change or modification in the device that could significantly affect the safety or effectiveness of the System 83 Plus, specifically as to the use of the filters with the connectors, and the changes or modifications you propose require a new 510(k). See 21 C.F.R. § 807.81(a)(3). Moreover, adding **b(4) CCI** as a correction to a process that has not been validated and has not been reviewed for safety and effectiveness provides 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.

5. You propose to provide users with a b(4) CCI [REDACTED] instructing users to take various steps b(4) CCI [REDACTED] to using the System 83 Plus, including reminders to users to:
 - a. Perform b(4) CCI [REDACTED] of water filter pressure differential before use;
 - b. Install a new disc filter onto reprocessing adapters [REDACTED] before use;
 - c. Check the MEC of the high level disinfectant b(4) CCI [REDACTED]; and
 - d. b(4) CCI [REDACTED].

This proposal is inadequate. Adding b(4) CCI [REDACTED] as a correction to address several processes that have not been validated provides 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.

II. Response to Custom Ultrasonics' Corrective Actions

As noted above, during the December 2015 meeting between FDA and Custom Ultrasonics, you sought to better understand the reasons that Custom Ultrasonics' corrective actions to date have failed to address the violations described in the Recall Order. We address your corrective actions below, after reciting each violation and nonconformance described in the Recall Order.

1. 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.

FDA reviewed Custom Ultrasonics' submissions and concludes that they inadequately address this violation. Your submissions lack evidence to support design validation of the System 83 Plus water filter assembly. The System 83 Plus uses a series of filters with a decreasing porosity to remove particulates and microorganisms from the incoming water supply. You stated that the device's filtration efficiency relied on

another manufacturer's 510(k)-cleared and validated bacterial retentive filters. Custom Ultrasonics has not validated the cascading filtration system to assure that it provides adequate filtration to prevent the release of waterborne or residual pathogens. You also have not submitted data to FDA to substantiate the instructions for use or performance claim for the water filtration assembly. Nor have you provided information to FDA (e.g., applicable procedures, SOPs, controls) to correct the firm's systemic design control issues related to the System 83 Plus water filtration system.

- 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.

We reviewed Custom Ultrasonics' submissions and conclude that they inadequately address this violation. You submitted the protocol and test results performed to validate that the replacement time (specified in the System 83 Plus Operator's Manual) is sufficient to ensure that the filtrate meet the porosity retention requirements of the disc filter for the recommended six-week time period. However, the study protocol does not appear to contain enough information to ensure that the validation was performed under defined operating conditions. Furthermore, it is unclear how you determined that the conditions used for the study protocol constitute actual use conditions representative of all conditions of use, rather than just the conditions at the hospital used for the study protocol. Additionally, you failed to submit information to demonstrate that you have established and maintained procedures to ensure that all System 83 Plus design functions are appropriately validated. Custom Ultrasonics also has not performed retrospective reviews to verify whether there are any other design specifications, features, or functions that need to be validated.

- 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.

We reviewed Custom Ultrasonics' submissions and conclude that they inadequately address this violation. You have proposed amending the devices' b(4) CCI to reflect that only b(4) CCI are to be used until further validation of other commonly used HLD's are provided to the agency." Your firm has not submitted adequate data to FDA that demonstrates the effectiveness of the specified HLD to support the change in the instructions for use. Nor have you provided information to FDA (e.g., applicable procedures, SOPs, controls) to correct the firm's systemic design control issues related to the use of HLDs in System 83 Plus for reprocessing of complex and non-complex endoscopes.

- 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.

We reviewed Custom Ultrasonics' submissions and conclude that they inadequately address this violation. Your firm has not provided adequate validation data to demonstrate the safety and efficacy of your device to assure adequate reprocessing of complex endoscopes. Nor have you provided information to FDA (e.g., applicable procedures, SOPs, controls) to correct the firm's systemic design control issues related to System 83 Plus compatibility to reprocess complex endoscopes.

2. 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).

We reviewed Custom Ultrasonics' submissions and conclude that they inadequately address this violation. Custom Ultrasonics has not submitted any servicing reports or related documentation in response to this violation. For example, Custom Ultrasonics has not provided to FDA relevant instructions or procedures for servicing System 83 Plus devices in the field or for verifying that servicing meets specific requirements for the System 83 Plus.

3. 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).

We reviewed Custom Ultrasonics' submissions and conclude that they inadequately address this violation. On January 16, 2015, your firm issued Technical Bulletin (TB-009), (Exhibit 20), a follow up to Technical Bulletin TB-007, to "describe the display functions of the UFAS Enhancement that is installed on the System 83 Plus that will visually alert the user of ultrasonic function during the wash and rinse phases." By letter, dated March 19, 2015, Custom Ultrasonics notified FDA's Philadelphia District Office that Custom Ultrasonics has "begun the retrofit of the System 83 Plus installed base with a visual status signal to the user indicating if failure of the ultrasonic generator board has occurred, i.e., loss of ultrasonics during the wash and all rinse phases of the System's operation." Custom Ultrasonics did not report the correction to FDA after

determining that it was a device enhancement. CDRH's Office of Device Evaluation, however, has concluded that the LED signal light was added to the System 83 Plus to address nonfunctioning ultrasonics. Such a change or modification in the System 83 Plus could significantly affect its safety or effectiveness and requires a new 510(k). See 21 C.F.R. § 807.81(a)(3).

Additionally, Custom Ultrasonics must submit a Report of Correction or Removal to FDA for this device change and update its procedures in accordance with 21 C.F.R. Part 806 Medical Devices; Reports of Corrections and Removals, and 21 C.F.R. Part 7, to ensure that all required information is provided. Custom Ultrasonics should also review FDA, Guidance for Industry and [FDA] Staff Distinguishing Medical Device Recalls from Medical Device Enhancements, available at <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm418469.pdf>.

The Recall Order also noted that Custom Ultrasonics 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.

Your firm's responses applicable to this nonconformance appear to be adequate. You acknowledge that an employee did not submit the MDR within the 30-calendar-day timeframe and represented that Custom Ultrasonics retrained its employees and corrected its "compliant coordination process" applicable to submitting MDRs to FDA.

III. Order of Appropriate Action

FDA hereby reaffirms the Recall Order. Further, in accordance with paragraph 5 of the Consent Decree, **FDA orders Custom Ultrasonics to immediately recall all System 83 Plus devices by removing them from use.** Custom Ultrasonics shall conduct the recall in accordance with 21 C.F.R. Part 7, and within ten (10) business days after receipt of this letter, shall notify FDA in writing at the address provided below, with all supporting documentation, of the specific actions Custom Ultrasonics has taken to implement the ordered recall. Additionally, as required by the Recall Order, Custom Ultrasonics must submit monthly reports to FDA, 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 the Recall Order. **FDA will assess liquidated damages for each day after February 8, 2016, that Custom Ultrasonics fails to initiate the recall described above and/or for each day the recall is not diligently implemented. FDA will also assess liquidated damages for each day after February 15, 2016, that Custom Ultrasonics fails to submit monthly reports to FDA.** 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 the Recall Order or any previously issued FDA order under the Consent Decree, and it shall be implemented consistent with, 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 yours,

A handwritten signature in black ink, appearing to read "S.M. Boyd", is written over a faint, light gray watermark of the FDA logo.

CAPT Sean M. Boyd, MPH, USPHS
Acting Director
Office of Compliance
Center for Devices and Radiological Health