FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

UNITED PARCEL SERVICE
OVERNIGHT DELIVERY

June 12, 2017

Alicia Nakonetschny, President
Custom Ultrasonics, Inc.
144 Railroad Drive
Ivyland, PA 18974

Re: Consent Decree of Permanent Injunction in *United States v. Custom Ultrasonics, Inc. et al.*, Civil Action No. 06-5267

Dear Ms. Nakonetschny:

This letter provides an update on the United States Food and Drug Administration's (FDA) review of the corrective actions that Custom Ultrasonics, Inc. (CUI) has taken in response to the April 9 and April 24, 2015 inspection of its facility located at 144 Railroad Drive, Ivyland, PA.

FDA most recently inspected your firm between April 25 and 28, 2017. The inspection evaluated, among other things, the corrective actions your firm has taken to address the previously observed violations and the validation records for testing that the automated endoscope reprocessors (AERs) can adequately wash and disinfect flexible endoscopes to mitigate the risk of patient infection. Based on our review of the inspection findings, CUI appears to have addressed the issues identified during the April 2015 inspection with regard to System 83 Plus Washer/Disinfector (including components and systems) for use in the reprocessing of flexible endoscopes that are not duodenoscopes.

Accordingly, the cessation of operations Order issued on September 5, 2012 pursuant to the Consent Decree of Permanent Injunction is hereby modified, and CUI may resume manufacturing, packing, and distributing its System 83 Plus Washer/Disinfector (including components and systems) provided it is marketed and labeled for use only in reprocessing flexible endoscopes that are not duodenoscopes (i.e., include a warning label specifying that the devices are not indicated for reprocessing of duodenoscopes), consistent with the May 2016 recall.

U.S. Food and Drug Administration
Office of Medical Device and Radiological Health Operations (Division 1)
One Montvale Avenue
Stoneham, MA 02180
www.fda.gov

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If you have any questions, or require additional information, please contact Richard C. Cherry, Compliance Officer, at (215) 717-3075; or richard.cherry@fda.hhs.gov.

Sincerely,

Joseph S. Matrisciano Jr -A

Digitally signed by Joseph S. Matrisciano Jr -A
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Joseph Matrisciano, Jr.
Program Division Director
Office of Medical Device and Radiological Health
Division 1

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