From: General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: FDA MedWatch - Endoscope Washer/Disinfectors by Custom Ultrasonics
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Endoscope Washer/Disinfectors by Custom Ultrasonics: Safety Communication - FDA Recommends Health Care Facilities Transition to Alternate Reprocessing Methods

AUDIENCE: Risk Manager, Gastroenterology, Pulmonology, General Surgery, Pharmacy

ISSUE: In accordance with a Consent Decree entered in January 2007 with Custom Ultrasonics, the FDA ordered Custom Ultrasonics to recall all of its Automated Endoscope Reprocessors (AERs) from health care facilities due to the firm's continued violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act), applicable regulations, and the Consent Decree. FDA is recommending that health care facilities currently using Custom Ultrasonics AERs transition away from their use to alternative methods to reprocess flexible endoscopes as soon as possible.

As part of the FDA's ongoing investigation into infections associated with reprocessed medical devices and AER devices used for cleaning and disinfection, the FDA has been reviewing the validation test methods and performance data for all AER manufacturers. To date, Custom Ultrasonics has not demonstrated that its AERs can adequately wash and disinfect endoscopes to mitigate the risk of patient infection.

The FDA's most recent inspection of the Custom Ultrasonics' facility in April 2015 documented continued violations. Violations include the inability to validate that the AERs can adequately wash and disinfect endoscopes to mitigate the risk of patient infection. The identified violations could result in an increased risk of infection transmission.

BACKGROUND: AERs are free-standing units used in health care facilities to disinfect flexible endoscopes and scope accessories between uses. Custom Ultrasonics AERs are intended to wash and high-level disinfect cleaned flexible endoscopes used in gastrointestinal and pulmonary tracts.

RECOMMENDATION: The FDA recommends that health care facilities currently using Custom Ultrasonics AERs transition away from their use to alternative reprocessing methods as soon as possible. Facilities are advised to:

- Identify and transition to alternate methods to reprocess flexible endoscopes, such as manual high-level disinfection, liquid chemical sterilization, alternative AERs, or other cleaning and sterilization methods according to the endoscope manufacturers’ reprocessing instructions.
- Before transitioning to an alternative method, be sure that the endoscopes your facility uses are compatible with the alternative method by referring to the endoscope manufacturer's reprocessing instructions.
- Submit a report to Custom Ultrasonics and to the FDA via MedWatch, as described below, if you suspect your health care facility's Custom Ultrasonics AER has caused or contributed to patient infection.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.

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