Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: November 18, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT/ Supervisor
Food Protection Program

SUBJECT: Custom Ultrasonics - [Medical Device]

AFFECTED PRODUCT: All Automated Endoscope Reprocessors (AERs)

SUMMARY: **Unclassified Recall; The U.S. Food and Drug Administration today ordered Custom Ultrasonics to recall all of its automated endoscope reprocessors (AERs) from health care facilities due to the firm's continued violations of federal law and a consent decree entered with the company in 2007. The identified violations could result in an increased risk of infection transmission.**

An estimated 2,800 AERs manufactured by Custom Ultrasonics are currently in hospitals and outpatient clinics throughout the United States. The FDA's recall order applies to all Custom Ultrasonics AERs, including the System 83 Plus, System 83 Plus 2 and System 83 Plus 9.

The recalled products were distributed throughout the United States.

SUGGESTED ACTION: **For consumer inquiry only. The safety communication issued by the FDA today recommends 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.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

FDA Orders Recall under Consent Decree for all Custom Ultrasonics Automated Endoscope Reprocessors

FDA Press Release

For Immediate Release

November 16, 2015

Contact
Firm Press Release

The U.S. Food and Drug Administration today ordered Custom Ultrasonics to recall all of its automated endoscope reprocessors (AERs) from health care facilities due to the firm's continued violations of federal law and a consent decree entered with the company in 2007. The identified violations could result in an increased risk of infection transmission. The FDA ordered this recall under the terms of the consent decree. The agency also issued a safety communication today 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.

These actions are part of the FDA's commitment to patient safety and ongoing efforts to minimize the risk of patient infections associated with reprocessed endoscopes, including duodenoscopes and scope accessories. The FDA has been working with federal partners, manufacturers and other stakeholders to better understand the critical factors contributing to bacterial infections associated with duodenoscopes and how to best mitigate them.

An estimated 2,800 AERs manufactured by Custom Ultrasonics are currently in hospitals and outpatient clinics throughout the United States. The FDA's recall order applies to all Custom Ultrasonics AERs, including the System 83 Plus, System 83 Plus 2 and System 83 Plus 9. Within seven business days after receiving the FDA's recall order, Custom Ultrasonics must provide a written recall proposal to the FDA.

"We are taking action because Custom Ultrasonics failed to meet its legal and regulatory obligations," said William Maisel, M.D., M.P.H., deputy director for science and chief scientist in the FDA's Center for Devices and Radiological Health. "The FDA's recall order stemmed from the company's continued violations of federal law and the consent decree and is necessary to protect the public health."

AERs are Class II medical devices that require 510(k) clearance and are used to wash and high-level disinfect endoscopes to decontaminate them between uses. AERs are designed to expose outside surfaces as well as interior channels of endoscopes to chemical solutions in order to kill microorganisms and prevent the spread of infection from these reusable medical devices. An endoscope must be thoroughly cleaned to remove any visible debris prior to placing it in an AER, which includes manually scrubbing the elevator mechanism and the recesses surrounding the elevator mechanism.

In 2012, under the terms of the consent decree, the FDA ordered Custom Ultrasonics to stop manufacturing and distributing all AER device models and components, and ordered their recall after the company failed to obtain FDA clearance following a significant change to the software operating system for one of its AERs. After Custom Ultrasonics obtained clearance for the significant change to the software operating system, the cleared devices were permitted to remain on the market. Since the 2012 order, the FDA has not authorized Custom Ultrasonics to resume manufacturing or distributing any AERs, though the company has continued to service them.

The FDA's most recent inspection of 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. In the months following the inspection, the FDA provided the company with an opportunity to correct inspection violations and requested additional validation data. Following a review of the company's submissions, the agency determined that Custom Ultrasonics has not adequately addressed its continued violations, which could result in an increased risk of infection transmission to patients.

Accordingly, under the terms of the consent decree, the agency today ordered Custom Ultrasonics to recall all of its AER devices.

The safety communication issued by the FDA today recommends 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. The safety communication is based on both the recent violations of the law and consent decree and reports that endoscopes reprocessed by Custom Ultrasonics' AERs have been used in health care facilities that reported the transmission of serious bacterial infections. Specifically, the FDA advises health care facilities currently using a Custom Ultrasonics AER to take the following actions:

- 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 manufacturer's reprocessing instructions.

- Before transitioning to an alternative method, verify that the endoscopes used by the facility 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 if the health care facility suspects that a Custom Ultrasonics AER has caused or contributed to patient infection.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Recall Order

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