BioSpectrum the business of Bio & Health Sciences

FDA issues guidelines for reusable medical devices

16 March 2015 | News | By BioSpectrum Bureau

FDA issues guidelines for reusable medical devices

The US Food and Drug Administration (US FDA) has announced new actions to enhance the safety of reusable medical devices.

The FDA's guidance document, titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling", includes recommendations medical device manufacturers should follow pre-market and post-market for the safe and effective use of reprocessed devices.

As part of its regulatory review for reusable medical devices, the FDA reviews the manufacturer's reprocessing instructions to determine whether they are appropriate and able to be understood and followed by end users. The guidance lists six criteria that should be addressed in the instructions for use with every reusable device to ensure users understand and correctly follow the reprocessing instructions.

It also recommends that manufacturers consider reprocessing challenges early in device design. Manufacturers will be expected to conduct validation testing to show with a high degree of assurance that their cleaning and disinfection or sterilization instructions will consistently reduce microbial contamination.

"Despite the recent concerns about multi-drug resistant bacteria infections associated with duodenoscopes, patients and health care providers should know that the risk of acquiring an infection from a reprocessed medical device is low," said Dr William Maisel, deputy director for science and chief scientist at the FDA's Center for Devices and Radiological Health.

He added, "This guidance is an important step toward further enhancing the safety margin by outlining for manufacturers the steps they should undertake to make their reprocessing instructions effective and clear to the healthcare community that uses them. Doing so should provide greater assurance to patients that the devices used on them are safe and effective."

The final guidance provides more clarity about testing protocols and data needs to be submitted to the agency for a pre-market submission.