MEDTECH INSIGHT
CITELINE COMMERCIAL

14 Mar 2018 | **News**

QUOTED. March 14, 2018. Jeff Shuren.

by

The head of US FDA's device center, Jeff Shuren, wants three manufacturers of duodenoscopes to fulfill their obligation to conduct post-market surveillance studies. Check out what he said about Olympus, Fujifilm and Pentax Medical here.

"FDA has taken important steps to improve the reprocessing of duodenoscopes, and we've seen a reduction in reports of patient infections, but we need the required post-market studies to determine whether these measures are being properly implemented in real-world clinical settings and whether we need to take additional action to further improve the safety of these devices. We expect these device manufacturers to meet their study obligations to ensure patient safety." –Jeff Shuren, director, US FDA Center for Devices and Radiological Health

Find out more: *FDA Warning Letters For Olympus, Fujifilm, Pentax: Duodenoscope-Makers Fail To Meet Agency's Post-Market Surveillance Study Order*