Nelson Laboratories Compliant With New FDA Medical Device Registration Requirement

The Associated Press

Nelson Laboratories (www.nelsonlabs.com) today announced compliance with the FDA Safety and Innovation Act (FDASIA) regarding updated requirements for the registration and listing of medical devices for contract sterilizers of non-exempt devices who do not commercially distribute product.

(Logo: http://photos.prnewswire.com/prnh/20120727/LA47745LOGO) "Nelson Laboratories is committed to staying up to date on the latest regulations from the FDA," said Sherri L. Robbins, Nelson Laboratories Director of Regulatory Affairs. "Because we provide ethylene oxide batch release sterilization services for exempt and non-exempt medical devices, and do not commercially distribute product, we now fall under this regulation. Therefore, we have completed our registration with the FDA as a device establishment." Part of this regulation change requires Nelson Laboratories to list the devices that they perform contract sterilization services on with the FDA. Contract sterilizers such as Nelson Laboratories can only complete a listing after the manufacturer has completed their own listing.

To know if you must register devices visit: http://bitly.com/d1zQgB To continue receiving batch release sterilization services without delay, Nelson Laboratories' non-exempt medical device manufacturers need to register their devices on the FDA webpage that details "How To Register and List." Before Nelson Laboratories can finish listing a device they will require the device exemption information for exempt devices, or for non-exempt devices, the 510(k), Premarket Approval (PMA) number and the proprietary marketed name of the device. Nelson Laboratories knows the importance of confidentiality and will always choose the "confidential" option when identifying the proprietary name of the device in FDA listing.

Anyone that has questions or needs additional guidance on registering a device can email Robbins at srobbins@nelsonlabs.com.

About Nelson Laboratories Nelson Laboratories is a leading provider of full, life-cycle microbiology testing services. We are known for exceptional quality, but we look beyond the testing process and partner with you to achieve your long-term business goals. It's what we call The Science of SuccessT. It's transparency in the testing process. It's approachable experts that guide you through ever-changing compliance requirements.

It's helping you mitigate risk, be first to market, and succeed with your customers. Learn more at www.nelsonlabs.com.

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