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SUMMARY

This was a CDRH/OMDRHI requested routine inspection of a medical device contract sterilizer and contract manufacturer conducted in accordance with compliance program 7382.845. This was a QSIT Level II inspection and covered the firm's management controls, corrective and preventive actions and production and process controls. The firm began doing contract packaging for customers in 2010. The firm is contract sterilizing medical device products by gamma irradiation.

The last inspection was made from March 4 to 7, 2024 and was a Biologics inspection of a registered human tissue establishment that processes human tissues as part of the Office of Biological Products Operations Compliance Program Guidance Manual (CPGM) 7341.002, Inspections of Human Cells, Tissues, Cellular and Tissue-based Products (HCT/Ps), to include Program Assignment Codes (PACs) 41002D. No FDA 483 was issued, and the inspection was classified as NAI.

The last medical device inspection was a PMA Preapproval Inspection of [redacted] and PMA Postmarket Inspection of [redacted]. The inspection was made from August 29 to 31, 2016 and no FDA 483 was issued, and it was classified as NAI.

At the conclusion of this inspection no FDA 483 was issued. Two minor issues were discussed at the conclusion of the inspection.