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SUMMARY

This model 2 baseline surveillance inspection of King Brand Healthcare Products was pre-announced and conducted under OMDRHI FY 26 work plan in accordance with CP 7382.850, Inspection of Medical Device Manufacturers. Time was claimed under PAC 82850B Baseline Surveillance Inspections, 81011 Medical Device Reporting, and 82016 Unique Device Identification. The eNSpect Operation ID is 348026. The firm is currently the manufacturer of a Class II device related to physical medicine. The Class II Blood Flow Stimulation Therapy (BFST) Knee Wrap is used for treatment of soft tissue injuries and chronic conditions in addition to aiding post-surgery recovery by increasing localized blood circulation. The firm receives incoming components from suppliers, assembles the devices on site, and ships finished devices to customers. The firm engages in design control activities for their device. Profile classes SPD and ELE were covered.

This inspection covered all 6 Quality Management System (QMS) areas and all Other Applicable FDA Requirements (OAFRs) applicable to the firm's operations, which include Medical Device Reporting (MDR), Reports of Corrections and Removals, and Unique Device Identification (UDI). Medical Device Tracking was not applicable as the firm's device has not been issued a tracking order by FDA. The inspection focused on the firm's BFST Knee Wrap device. A 6-item form FDA 483, Inspectional Observation was issued to Mr. Scott A. West, President, citing the following observations: