Safety Communication رسالة سلامة

Potential of toxicological risks to patient

Device/ Product Description:	Precice Intramedullary limb lengthening (IMLL) device system
Affected product:	All Precice System Devices, including: Precice Intra-medullary limb lengthening device (IMLL), Precice Short, Precice Unyte, Precice Freedom, Precice Opty-line, Precice Bone Transport, Precice Plate, and Precice Stryde.
Manufacturer:	Nuvasive Specialized Orthopaedics
Problem:	Potential of toxicological risks to patient under 22 kg or for patients with more than two implanted devices.
Recommendation /Actions:	IFU for Precice IMLL System devices has been updated to include: - Clarity on indication for use in adults; - Warning that no more than two (2) devices should be implanted at one time and a patient must be greater than 22kg; and - Addition of Potential Adverse Events section. For more information, please click here. If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999)unified call center

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