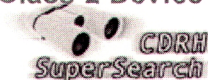




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**Class 2 Device Recall Nexstim**

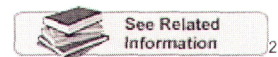


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**Class 2 Device Recall Nexstim**



<b>Date Initiated by Firm</b>	March 14, 2017
<b>Date Posted</b>	May 22, 2017
<b>Recall Status</b> <sup>1</sup>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-2320-2017
<b>Recall Event ID</b>	<a href="#">77198</a> <sup>23</sup>
<b>510(K)Number</b>	<a href="#">K112881</a> <sup>24</sup>
<b>Product Classification</b>	<a href="#">Stimulator, electrical, evoked response</a> <sup>25</sup> - <b>Product Code</b> <a href="#">GWF</a> <sup>26</sup>
<b>Product</b>	NBS System 4 (sw version 4.0 or higher), Software update to 4.3.3 and NBS System 5 (sw version 5.0 or higher), Software update to 5.1.1. The Nexstim Navigated Brain Stimulation System (NBS System) is indicated for noninvasive mapping of the primary motor cortex of the brain to its cortical gyrus. The NBS System provides information that may be used in the assessment of the primary motor cortex for pre-procedural planning. The NBS System is not intended to be used during a surgical procedure. The NBS System is intended to be used by trained clinical professionals.
<b>Code Information</b>	Serial numbers: NBS10391245N4, NBS11011250N4, NBS11071252N4, NBS11201252N4, NBS11451264N4, NBS11491268N4, NBS12051269N4, NBS12261274N4, NBS12341276N4, NBS12441278N4, NBS13341282N4, NBS13431283N4, NBS13451284N4, NBS13481286N4, NBS14011288N4, NBS14361295N5, NBS14481298N5, NBS14491299N5, NBS14511301N5, NBS15131302N5, Serial numbers: NBS10391245N4, NBS11011250N4, NBS11071252N4, NBS11451264N4, NBS11491268N4, NBS12051269N4, NBS12261274N4, NBS12341276N4, NBS12441278N4, NBS13341282N4, NBS13431283N4, NBS13451284N4, NBS14011288N4, NBS14481298N5, NBS14491299N5, NBS14511301N5, NBS15131302N5, NBS15271305N5, NBS15371307N5, NBS16031313N5 and NBS16221316N5. Additionally in Nexstim's warehouse (i.e. not distributed NBS 11201256N4, NBS 13481286N4, NBS 14361295N5 and NBS 16371318N5) .
<b>Recalling Firm/ Manufacturer</b>	Nexstim PLC Elimaenkatu 9B Helsinki Finland
<b>For Additional Information Contact</b>	312-373-3704
<b>Manufacturer Reason for Recall</b>	Software defect: the NBS software may accidentally generate duplicate copies of one or several files.
<b>FDA Determined Cause</b> <sup>2</sup>	Use error
<b>Action</b>	DePuy Synthes sent an Urgent Information Recall Notice dated January 6, 2017, to all affected consignee. The letter identified the product, the problem, and the action to be taken by the consignee. Consignees were instructed to immediately inspect their inventory and return the affected instruments. . If the medical facility is using an instrument that was created or modified by a DePuy Distributor at the request of a surgeon and it is not listed on