Class 2 Device Recall Satellite Spinal System Primary User Group Reference Guide

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See Related Information[23]

Date Posted	December 22, 2007
Recall Status[1]	Terminated on August 18, 2009
Recall Number	Z-0192-2008
Recall Event ID	44967[24]
Premarket Notification 510(K) Number	K051320[25]
Product Classification	Intervertebral Fusion Device With Bone Graft, Solid-Sphere, Lumbar[26] - **Product Code** NVR[27]
Product	Satellite Spinal System Primary User Group Reference Guide, 8 1/2 by 11 inch plastic binder, Medtronic Sofamor Danek, Medtronic, Memphis, TN 38132
Code Information	All manuals; the manual were not coded.
Recalling Firm/ Manufacturer	Medtronic Sofamor Danek USA Inc 1800 Pyramid Place Memphis, Tennessee 38132-1719
For Additional Information Contact	Bert Kelly 901-396-3133
Manufacturer Reason for Recall	Surgical manual lacks information required as a condition of the 510(k) approval.

FDA Determined Cause [2]	DESIGN: Labeling Design
Action	On September 12, 2007, the recalling firm's representatives were instructed by electronic mail to remove any manuals in the field and contact surgeons who have evaluated, implanted or been trained to implant the Satellite System and to collect any guides they may have on site. The sales representatives that have accounts where the Satellite product was shipped directly were mailed the information and instructed to hand deliver the 9/13/07, Urgent Device Recall notices to each consignees risk management office. The recall was then expanded on 10/31/2007, to include the surgical manual, the implants and associated instruments. The delivery of the second Urgent Device Recall Notices, dated 10/25/07, were handled in three ways: 1) The letter was delivered to all initial consignees that received satellite products along with a questionnaire (response card) to be completed by the Risk Manager or equivalent administrative function., 2) The letter without the questionnaire was sent directly to target surgeons who are known to have implanted or have been trained to implant Satellite Product 3) a field action confirmation form was sent to Sales Representative with surgeon customers that are receiving the recall communication. The form will be completed by the Sales Representative to confirm the surgeons have received the recall communication and have returned any of the surgical techniques and instruments.
Quantity in Commerce	approxmately 200 to 300
Distribution	Nationwide
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database

510(K)s with Product Code = NVR and Original Applicant = MEDTRONIC SOFAMOR DANEK[30]

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
23. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
24. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=44967
25. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K051320
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NVR
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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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Silver Spring, MD 20993
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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
23. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
24. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=44967
25. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K051320
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