Drill Guide, used with a Medtronic...

The topic: Issuance of a continuous monitoring equipment...

The purpose:
- Drill Guide, used with a Medtronic Computer Assisted Surgery System to help assist with screw placement during spine surgical procedures.
- Trade Mark: Medtronic Navigation Inc
- Local Representative:

Based on the report issued by the medical establishment,

which is valuable in the process of manufacturing the mentioned company, we are notified to inform all concerned parties about this equipment.

Attached:
- FDA's directive regarding the establishment.
- Information on the issuing of the mentioned party.
- Review of the program and the project
- Governmental departments and establishments
- Notifications.
Drill Guide, used with a Medtronic.

الموضوع: إشعار بمتابعة جهاز طبي.

المكان المعني بالموافقة:

- Drill Guide, used with a Medtronic Computer Assisted Surgery System to help assist with screw placement during spine surgical procedures.
- Trade Mark: Medtronic Navigation, Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة الـ fda،

الذي يفيد بوجود خلل في تصنيع الصفن المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع الأطباء.

مرفق بطاقة:

- التوصية الصادرة عن وكالة الـ fda
- متابعة
- دائرة البرامج والمشاريع
- المستندات الحكومية
- المحفوظات

الرقم المحفوظات: 191
رقم الصادر: 1976
بيروت، في: 5- كانون الثاني 2012
جانب تقبع الطابع في الشمال/طرابلس
جانب نقيب الأطباء في لبنان/بيروت

الموضوع: إشعار بمتابعة جهاز طبي

الجهاز المعني بالمتاحة:

- Drill Guide, used with a Medtronic Computer Assisted Surgery System to help assist with screw placement during spine surgical procedures.
- Trade Mark: Medtronic Navigation Inc
- Local Representative:

بناءً على التقرير الصادر عن وكالة fda، الذي يفيد بوجود خلل في تصنيع الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع الأطباء.

مرفق ربط:

- التوصية الصادرة عن وكالة fda

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات
Medical & Radiation Emitting Device Recalls

U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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Date Posted
November 29, 2012

Recall Number
Z-0441-2013

Product
The Vertex Max Drill Tube is a component within the Navigated Vertex Max Drill Guide Set (item 9733270). The Navigated Vertex Max Drill Guide Set is intended to be used with a Medtronic Computer-Assisted Surgery System to help assist with screw placement during spine surgical procedures. The device is reusable and requires sterilization according to product labeling.

Code Information
Lot number 120203.

Recalling Firm/Manufacturer
Medtronic Navigation, Inc.
826 Coal Creek Cir
Louisville, Colorado 80027-9710

Reason for Recall
Medtronic is recalling certain Vertex Max Drill Tubes which are used with the StealthStation System due to a defect related to the internal threading for component set up.

Action
Medtronic Navigation sent a Urgent Medical Device Recall letter dated November 13-14, 2012, to all affected customers. The letter identified the product, the problem, and the action needed to be taken by the customer. Customers were instructed do not use the Vertex Max Cannulated Drill Tube clinically. Medtronic Navigation will remove the Vertex Max Cannulated Drill Tube. Medtronic Navigation will provide a replacement Vertex Max Cannulated Drill Tube manufactured from a different lot which was inspected to verify the defect has been corrected. If you have any questions about this notification, please contact a Sales Representative in your area. For further questions please call (720) 890-3200 Ext. 3303.

Quantity in Commerce
12 Units

Distribution
Worldwide Distribution--US (nationwide) including the states of CA, FL, MA, LA, and MI and the countries of Switzerland, Saudi Arabia, Lebanon, Canada and Korea.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ../cfMMN/pm.cfm
8. ../cfIR/h.cfm
9. ../cfMAUDE/TextSearch.cfm
10. ../cfRES/res.cfm
11. ../cfPMA/pma.cfm
12. ../cfPCD/classification.cfm
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15. ../cfPCD_RH/classification.cfm
16. ../cfAssam/assembly.cfm
17. ../Medsun/searchReportText.cfm
18. ../cfCle/Search.cfm

12/12/2012