New Search

Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the original PMA to get an up-to-date view of this device.

Device Classification Name: CAPSUREFIX(R)
Generic Name: Permanent Pacemaker Electrode
Regulation Number: 870.3680
Applicant: MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT
8200 Coral Sea Street N.E.
Mounds View, MN 55112
PMA Number: P930039
Supplement Number: S009
Date Received: 03/13/2000
Decision Date: 08/31/2000
Product Code: DTB
Advisory Committee: Cardiovascular
Supplement Type: Normal 180 Day Track Change
Supplement Reason: Design/Components/Specifications/Material
Expedited Review Granted?: No
Combination Product: No

Recalls

Approval for an extendable/retractable screw-in pacing lead. The device, as modified, will be marketed under the trade names medtronic capsure(r)fix novus model 5076 and vitatron crystalline(r) actfix model icf09 pacing leads. These devices are indicated for permanent pacing and sensing of the ventricle and/or atrium when used with a compatible pulse generator.

Approval Order Statement

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfCLIA/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. /scripts/cdrh/cfdocs/cfPMA/pma.cfm