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Premarket Approval (PMA)



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Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the [original PMA](#)²³ to get an up-to-date view of this device.

Device	CAPSUREFIX(R)
Classification Name	Permanent Pacemaker Electrode ²⁴
Generic Name	Permanent Pacemaker Electrode
Regulation Number	870.3680 ²⁵
Applicant	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT 8200 Coral Sea Street N.E. Mounds View, MN 55112 P930039
PMA Number	S009
Supplement Number	03/13/2000
Date Received	08/31/2000
Decision Date	DTB [Registered Establishments With DTB ²⁶]
Product Code	Cardiovascular
Advisory Committee	Normal 180 Day Track
Supplement Type	Change
Supplement Reason	Design/Components/Specifications/Material
Expedited Review	No
Granted?	No
Combination Product	No

Recalls

[CDRH Recalls](#)²⁷

Approval Order Statement

Approval for an extendable/retractable screw-in pacing lead. The device, as modified, will be marketed under the trade names medtronic capture(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.

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