



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: November 21, 2003
From: Humanitarian Device Exemptions (HDE) Staff, ODE, CDRH
(HFZ-403)
Subject: HDE Approval Package (H020003)
To: Dockets Management Branch (HFA-305)

Attention:

Jennie Butler
Lyle Jaffe
Gloria Ortega

The following HDE application was recently approved:

HDE Number: H020003
Docket Number: 03M-0536
Device Name: CONTEGRA® Pulmonary Valved Conduit
Applicant: Medtronic, Inc.

Attached is the following information for this HDE:

Approval Order
Summary of Safety and Probable Benefit
Labeling

If you have any questions, please call me at (301)594-1190
ext. 110.

Paul A. Williams

Attachments

2003M-0536

AAV 1