



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: September 14, 2004
From: Humanitarian Device Exemptions (HDE) Staff, ODE, CDRH (HFZ-403)
Subject: HDE Approval Package (H030009)
To: Dockets Management Branch (HFA-305)

Attention:

Lyle Jaffe
Jennie Butler
Gloria Ortega

The following HDE application was recently approved:

HDE Number: H030009
Docket Number: 2004M-0415
Device Name: Vertical Expandable Prosthetic Titanium Rib
(VEPTR)
Applicant: Synthes (USA)

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. 107.

Marsha Melvin

Attachments

2004 M-0415

AAV'