



Memorandum

Date: August 8, 2005
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From: Humanitarian Device Exemptions (HDE) Staff, ODE, CDRH (HFZ-403)
Subject: HDE Approval Package (H050001)
To: Division of Dockets Management (HFA-305)

Attention:

Jennie C. Butler
Lyle D. Jaffe
Gloria M. Ortega

The following HDE application was recently approved:

HDE Number: H050001
Docket Number: 2005M-0308
Device Name: Wingspan Stent System with Gateway PTA Balloon Catheter
Applicant: Boston Scientific Smart

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.

Sheila A. Brown

Attachments

2005M-0308

AAV1