



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: APR -7 2004

From: Humanitarian Device Exemptions (HDE) Staff, ODE, CDRH
(HFZ-403)

Subject: HDE Approval Package (H020008)

To: Dockets Management Branch (HFA-305)

Attention:

Jennie Butler
Lyle Jaffe
Gloria Ortega

The following HDE application was recently approved:

HDE Number: H020008
Docket Number: 04M-0165
Device Name: OP-1 Putty
Applicant: Stryker Biotech

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

2004M-0165

AAV1