

Sawyer-Major, Wanda

From: Sawyer-Major, Wanda
Sent: Friday, January 09, 2004 8:54 AM
To: Jaffe, Lyle D
Subject: FW: P000048

Hi Lyle,

Please see the message below. I'll be sending you a corrected version as well. Thanks.

Wanda Sawyer-Major

Program Support Specialist
Program Operations Staff - PMA Section
301-594-2186 ext. 105

-----Original Message-----

From: Sawyer-Major, Wanda
Sent: Friday, January 09, 2004 7:41 AM
To: Racine, David W.; Gagne, Stefan
Cc: Peterson, David*
Subject: P000048

Hi David,

Sometime ago, we had this approval package pulled from the web for corrections. It's finally completed so I'll send the updated approval package to IMAGE this morning. Thanks.

Wanda Sawyer-Major

Program Support Specialist
Program Operations Staff - PMA Section
301-594-2186 ext. 105

UPDATED APPROVAL PACKAGE

**Premarket Approval (PMA) Package for
Dockets Management Branch**

**PMA Number P000048
Docket # 2002M-0034**

**Dornier Medical Systems, Inc.
Dornier Epos™ Ultra**

Includes:

**Approval Order
Summary of Safety and Effectiveness Data (SSED)
Labeling**