Howard C Thomas

From: FDA Radiological Health Electronic Submission Program [cdrhesub@cdrh.fda.gov]

Sent: Friday, October 24, 2008 2:17 PM

To: howard@collimare.com

Subject: Acknowledgement of Medical Laser Products Initial Product Report, 0810482-000

This message confirms receipt of the Radiation Safety Report identified below. While this does not constitute approval of the document, it does acknowledge your submission of a complete report, fulfilling FDA reporting requirements in Title 21, Code of Federal Regulations (CFR), Part 1002.

- - - - - - - - - - DOCUMENT RECEIVED, FILED, & ACKNOWLEDGED - - - - - - - - - -

This automated notification from the CeSub Submission Process contains general information about the aforementioned submission:

Accession Number: **0810482-000**
Date Loaded: **Oct 24, 2008**
Document Date: **Oct 9, 2008**
Establishment Name: **COLLIMARE, LLC**
Purpose: **This submission is a(n) Initial Product Report. These Medical Laser Products include designated model family Collimators (beam limiting devices) with model(s) Collimare.**

Submitter: **Howard C Thomas**
Email: **howard@collimare.com**
Reporting Official: **Howard C Thomas**
Email: **howard@collimare.com**
- -

If you meet all other applicable FDA requirements, you may market the product(s) reported. Please be aware that additional electronic product radiation control or medical device regulations may apply to your product, such as:

21 CFR 1010 - 1050, requiring certification to FDA radiation safety performance standards

21 CFR 807, requiring manufacturer registration and device listing, and

21 CFR 807, 812 and 814, requiring medical device clearance or approval.

If any questions or concerns arise during our review of your report, we will notify you. If you have any questions, contact us at 240-276-3332.

Sincerely Yours,

CDR Sean M Boyd
Electronic Products Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs
http://www.fda.gov/cdrh/radhealth