

K971290
June 20, 1997

510(k) Summary

SUBMITTER:

Submitted on behalf of:

Company Name: **STRATASYS, Inc.**
Address: 14950 Martin Drive
Minneapolis, MN 55344-2020

by: **Paladin Medical, Inc.**
P.O. Box 560
Stillwater, MN 55082

CONTACT PERSON: Elaine Duncan

DATE SUMMARY PREPARED: April 3, 1997

TRADE NAME: Stratasys FDM® MedModeler System
COMMON NAME: Radiology Accessory

SUBSTANTIALLY EQUIVALENT TO: The Stratasys FDM MedModeler System is substantially equivalent to the SurgiCAD image processing accessory accepted under premarket notification K924630.

DESCRIPTION of the DEVICE: The Stratasys FDM MedModeler produces anatomical models for use in a variety of medical applications using CT and MRI imaging data. The four main parts of the FDM system, as displayed in Figure 1 (previous page) are 1) the QuickSlice Software, 2) FDM Hardware, 3) Modeling Materials and a 4) Computer Workstation.

INDICATIONS FOR USE: The Stratasys FDM MedModeler is indicated as an image processing accessory, used to create three dimensional models from 3D surface representation data or 2D contour data as a diagnostic tool, as a pre-operative planning tool, and to enhance communication with patients, other professionals or students.

CLINICAL INFORMATION and SAFETY and EFFECTIVENESS: Hazard/Risk Analysis demonstrates that the safety of the Stratasys FDM MedModeler is acceptable and that identified potential risks are within acceptable limits for likelihood of occurrence and severity of hazards. The model generation report demonstrates that the FDM MedModeler performed as intended and within system requirements for CAD, CT and MRI image modeling, and produced satisfactory models. Software development information, software validation and hardware validation information are also provided according to FDA guidance requirements.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

Stratasys, Inc.
c/o Elaine Duncan, RAC, M.S.M.E.
President
Paladin MedicalSM, Inc.
P.O. Box 560
Stillwater, MN 55082-0560

Re: K971290
Stratasys FDM@ MedModeler System
Radiology Accessory
Dated: April 3, 1997
Received: April 7, 1997
Unclassified/Procode: 90 LLZ

Dear Ms. Duncan:

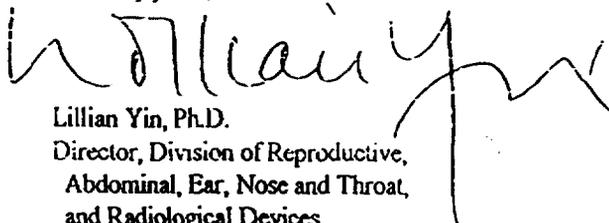
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K971290

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(Please Do Not Write Below This Line-Continue On Another Page If Needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use

(Optional Format 1-2-96)

David H. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971290