

7474455

Summary

Device Safety & Effectiveness

FEB 20 1998

Safety:

As evident from the enclosed device description, Anatom 1000 is a stand-alone device. It is intended that the system will be operated under the control of qualified clinicians only, while a patient is being examined. The operators should be healthcare professionals familiar with and responsible for the CT studies to be performed. All of the system's X-ray components are certified to be in compliance with the Federal Diagnostic X-ray Equipment Performance Standard. The enclosed device labeling and instructions provide the operator(s) with the knowledge required to safely use the Anatom 1000 system.

To minimize electrical and mechanical, as well as radiation hazards, Analogic adheres to FDA GMPs, recognized and established industry practices, and all equipment is subject to final on site performance testing which is carried out by qualified field service engineers. The system will be certified to both national and international safety standards, i.e. UL2601, CSA 22.2 No. 601.1 and IEC 601-1, and other collateral standards for radiation protection, patient support equipment and PEMS.

Use of the Anatom 1000 does not contribute any additional risk to the patient or operator, but provides the radiologist with recognized benefits of CT imaging technology.

NOTE: An automatic systems test is performed every time the Anatom 1000 system is powered up. In addition, a separate image quality test can be performed from the operator console in the control room before each use.

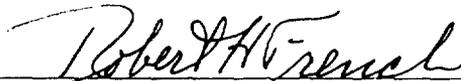
EFFECTIVENESS:

Based on Analogic's evaluation throughout all development phases of the Anatom 1000 system, and verification/validation of software programs involved, the product will perform in accordance with original product development objectives. The Anatom 1000 represents state-of-the-art technology and, therefore, is equivalent to other similar products already cleared by the 510(k) process.

At this time, we are unable to find any information regarding any new adverse effects for this type of equipment. A risk assessment and hazards analysis have been ongoing throughout the system's design, development and manufacturing processes which have taken into account older or previously reported problems initially discovered with older designs for this type of equipment.

Analogic Corporation
Vice President Corporate QA & RA, Customer Service Division

Robert H. French



(Date) November 24, 1997

(Signature)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 20 1998

Robert H. French
Vice President
Corporate QA & RA
Customer Service Division
Analogic Corporation
8 Centennial Drive
Peabody, MA 01960

Re: K974455
Anatom 1000 (A minus, A-) Computed Tomography System
Dated: November 24, 1997
Received: November 25, 1997
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. French:

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 Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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): _____

Device Name: Anatom 1000

Indications for Use:

The Anatom 1000 system is intended to be used as a diagnostic x-ray device, for the purpose of obtaining cross-sectional images of the whole body by computer reconstruction of X-ray data, from the same axial plane taken at different angles.

This device includes signal analysis and display equipment, patient and equipment supports, component parts and accessories. Additionally, the Anatom 1000 system can be field upgraded to either an "A" system or an "HA+" system which includes the capabilities of Helical Scanning (Volumetric scanning) and MPR (Multi-planar Reconstruction).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109)

OR

over-the-counter Use _____

(Optional Format 1-2-96)

David C. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974455