NOV - 9 1999

SECTION 10: 510(K) SUMMARY

K 992740

Name and Address of Manufacturer:	Imatron, Inc. 389 Oyster Point Blvd. South San Francisco, CA 94080
Contact:	J.A. Coduto Director of Regulatory Affairs Phone: 503-638-5500 FAX: 503-638-6328 email: jcoduto@imatron.com
Establishment Registration Number:	2936804
Common and Proprietary Names:	Common Names: CT scanner system; Computed tomography X-ray system; Electron beam scanner system; Scanner system; CT angiography system; Electron beam angiography system Proprietary Name: EBT Ultrafast® CT scanner system; Ultrafast CT scanner system; C-100, C-150, C-150LXP or C-150XP scanner systems
Device Class:	Class II
Classification Name:	21 CFR 892.1750/Procode: 90 JAK Computed tomography x-ray system 21 CFR 892.1600/Procode: 90 IXI Angiography x-ray system
Performance Standards:	The Imatron EBT scanner system meets the applicable requirements of the FDA Performance Standard for Ionizing Radiation Emitting Products (i.e., 21 CFR Sections 1020.30, 1020. 31, 1020. 32, and 1020.33).

Device Description:

Imatron's current EBT scanner system, i.e., the CT system to be used for CT Angiography, is composed of essentially two subsystems, i.e., a CT scanner (and its associated components, parts, and accessories) and a workstation (and its associated components, parts, and accessories). Imatron's scanner operates by directing a focused beam of electrons along tungsten target rings to produce X-rays which pass through the human body at multiple angles as in conventional CT scanning systems. Such EBT scanner is capable of producing CT slices at rapid speeds since the data is produced by electronic rotation of the electron beam itself rather than the mechanical rotation of an X-ray tube as in conventional CT scanning systems. The EBT system's workstation is either directly incorporated into and physically a part of the system or is indirectly incorporated into the system via a data connection port. Such workstations are all able to receive EBT cross-sectional images (either through a direct connection or through a DICOM 3.0 or higher compatible interface) and have a cleared intended use which includes being able to produce 3 and/or 4 dimensional volume imaging (including, among other functions, volume rendering, surface rendering, maximum intensity projections, or reformatting).

Intended Use:

The Imatron EBT scanner system -- when used angiographically -- is intended to combine the capabilities of both a CT and angiography system. When used for this purpose, the system is intended to perform Electron Beam Angiography, i.e., "EBA".

More specifically, the EBT system is intended:

1. to function as a diagnostic x-ray system to produce two and three dimensional images of the heart, blood vessels, or lymphatic system from a volume of computer reconstructed cross-sectional images from x-ray transmission data from the same axial plane taken at different angles;

2. to permit radiologic visualization during or after injection of a contrast medium; and

3. to permit the transmission data from certain three dimensional images to also be presented in time-sequenced or cine fashion.

Finally, such system is intended to be used consistent with those already classified and set forth in 21 CFR Sections 892.1600 and 892.1750.

Technological Characteristics:

The Imatron EBT scanner system is a combination of a CT and an angiography system.

General Safety and Effectiveness Concerns:

The Imatron EBT scanner system and its components are subject to the Federal Diagnostic Equipment Performance Standard and applicable requirements of 21 CFR Sections 1020.30, 1020.31, 1020.32 and 1020.33 and are certified to meet those requirements. All reports required for such new device have been filled with CDRH. To minimize electrical, mechanical, and radiation hazards, Imatron complies with pertinent recognized and established industry practice, including ISO 9001: Quality System (ANSI/ASQC 29001-

1994); EN 46001: Application of EN ISO 9001 To The Manufacture Of Medical Devices; EN 60601-1 Electrical-Technical Safety; Council Directive 93/42/EEC: Medical Device Directive; and Council Directive 89/336/EEC: Electro-Magnetic Compatibility.

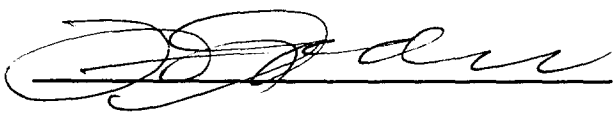
Substantial Equivalence:

A computed tomography x-ray system is defined as a diagnostic x-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. (21 CFR Section 892.1750). This generic type of device may also include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. The Imatron EBT scanner system here in question is not just substantially equivalent to the "1750" systems; it is identical to the prior Imatron Ultrafast CT scanner system which has been repeatedly cleared by FDA as being a "1750" device and, thus, able to be offered for sale in interstate commerce. There are no differences between the two device systems (except that the focus of this submission is to be used for CT Angiography).

An angiographic x-ray system is defined as a device intended for radiologic visualization of the heart, blood vessels, or lymphatic system during or after injection of a contrast medium. (21CFR Section 892.1600). This generic type of device may also include signal analysis and display equipment, patient and equipment supports, component parts and accessories. As indicated above, the CT scanner system here in question has already been cleared (various times) as a CT x-ray system under Section 1750. It logically follows then that such system is 1. an x-ray system, 2. a device intended for radiologic visualization, and 3. capable of producing x-ray images of the heart, blood vessels and lymphatic system (since all "1750" devices are cleared to x-ray

image every part of the human "body"). CT scanner systems (i.e, "1750" systems) have been used for decades in association with contrast media; thus, that use too is an inherent use within the scope of current clearance of a "1750" device.

Thus, the Imatron EBT scanner system here in question is substantially similar to all "1600" type devices. It differs principally only in its ability to function in "UltraFast" fashion, i.e., to take its images faster than does a typical scanner system.



8-12-99

J.A. Coduto
Director of Regulatory Affairs

Date:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 1999

J.A. Coduto
Director, Regulatory Affairs
Imatron, Inc.
389 Oyster Point Blvd.
South San Francisco, CA 94080-1998

Re: K992740
EBT UltraFast® CT Scanner System;
UltraFast CT Scanner System; C-100,
C-150, C-150LXP or C-150XP Scanner
System
Dated: August 12, 1999
Received: August 16, 1999
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK
21 CFR 892.1600/Procode: 90 IZI

Dear Mr. Coduto:

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 legally marketed predicate 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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): K992740

Device Name: EBT ULTRAFAST® CT SCANNON SYSTEM, ULTRAFAST CT SCANNON SYSTEM, C-100, C-150, C-150LXP OR C-150XP SCANNON SYSTEMS

Indications For Use:

The Imatron EBT scanner system -- when used angiographically -- is intended to combine the capabilities of both a CT and angiography system. When used for this purpose, the system is intended to perform Electron Beam Angiography, i.e., "EBA".

More specifically, the EBT system is intended:

1. to function as a diagnostic x-ray system to produce two and three dimensional images of the heart, blood vessels, or lymphatic system from a volume of computer reconstructed cross-sectional images from x-ray transmission data from the same axial plane taken at different angles;

2. to permit radiologic visualization during or after injection of a contrast medium; and

3. to permit the transmission data from certain three dimensional images to also be presented in time-sequenced or ciné fashion.

Finally, such system is intended to be used consistent with those already classified and set forth in 21 CFR Sections 892.1600 and 892.1750.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jeremias

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992740

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)