

OCT 15 1997

510(K) SUMMARY

Submitter's Name: Imatron, Inc.

Address: 389 Oyster Point Blvd.
South San Francisco, CA 94087

Phone(s): (O) 415-583-9964, ext. 206
(F) 415-827-7790

Contact Person: J.A. Coduto

Date: August 1, 1997

Common Names: CT Scanner; Computed Tomography X-ray System

Proprietary Names: Ultrafast® CT Scanner; EBT CT Scanner, Evolution

Classification Name: Computed Tomography X-ray System

Predicate Device: Imatron Ultrafast CT Scanner (K913352/A)

Device Description: The Imatron Ultrafast CT scanner is a scanning system which operates by directing a focused beam of electrons along tungsten target rings to produce X-rays which pass through the body at multiple angles as in conventional CT scanning systems.

The Imatron Ultrafast CT 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.

Currently, the Imatron Ultrafast CT scanner operating at its highest resolution mode has 864 single, contiguous X-ray detectors subtending an arc of 0.250 degrees each. The resulting 5% amplitude modulation transfer function (MTF) for high contrast objects at the center of the circle of reconstruction is 7 line pairs per centimeter (lp/cm).

Proposed Design Modification

The primary purpose of this submission is to provide notification of a proposed design modification to the above-referenced detector system. This modification, in the aggregate, is called the High Resolution Detector (HRD). Similar to the current system, the HRD retains the original dose efficiency, the same number of data acquisition channels, and the same number of samples. It differs from the current system in that it now consists of **864 pairs** of contiguous detectors subtending an arc 0.125 degree width. In the modified system odd numbered detector outputs (i.e., one half of each of the 864 pairs) are electronically delayed 60 microseconds, the time required for an object shadow to move one detector's width. This is defined by Imatron as the Time to Next Detector (TND). In the modified system each delayed output is summed with its even numbered, undelayed partner's. The resulting 5% amplitude MTF is 9.5 lp/cm.

Other Modifications

Additionally, this notification also sets forth the numerous, nonsignificant modifications made since Imatron's last 510(k) filing with the Agency (i.e., on July 26, 1991; see K913352/A). As indicated in tables contained herein (and subsequently referenced and discussed), Imatron believes such modifications have not significantly impacted the safety, effectiveness, or intended use of the device, and, thus, they did not need to be the subject of premarket notification.

Intended Use:

The intended use of the device here in question, i.e., the Imatron Ultrafast CT Scanner, remains unchanged from the intended use of prior predicate Imatron and other scanners. The Imatron Ultrafast CT Scanner is designed -- as are all similar devices -- to produce cross sectional images (i.e., thin slices) of the human anatomy. In this instance, such images are produced via helical (i.e., continuous

)

volume or dynamic) or stationary (i.e., static) scanning. Imatron's device is -- as are some of the predicate devices -- also intended to be used for clinical situations requiring determination of specific quantitative information, such as the determination of calcium or other materials in bone, tumors, or organs.

Technological Characteristics:

See attached Substantial Equivalence Comparison Table and Table of Explanation of Differences.

Non-clinical Performance:

In order to assure proper product performance, including reliability, and demonstrate substantial equivalence of the modified scanner here in question to the predicate scanner, the modified scanner was extensively bench tested. Such finished testing included approximately 61 tests to determine conformance with numerous performance specifications, including four product acceptance tests and 12 product release criteria tests. Also included was phantom testing to assure the requisite quality of the finished X-ray product.

)

Clinical Performance:

After successfully completing bench testing such modified device was then used for human volunteer testing – pursuant to IRB overview and informed consent. Such testing was conducted on site, and incorporated use of twelve human subjects. Again, the device was demonstrated to be substantially equivalent.

Testing Conclusions:

The above-referenced tests indicated that the device as modified is substantially equivalent to the predicate device.



OCT 15 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850J.A. Coduto
Director, Regulatory Affairs
Imatron, Inc.
389 Oyster Point Blvd.
South San Francisco, CA 94080Re: K972879
Ultrafast Computed Tomography Scanner
Models C-150XP and C-150LXP with
High Resolution Detector
Dated: August 4, 1997
Received: August 5, 1997
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

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 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,

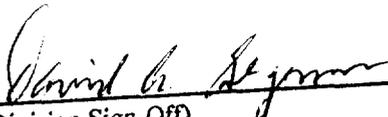
Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: PROPOSED LABELING

D. PROPOSED INTENDED USE STATEMENT

The intended use of the device here in question, i.e., the Imatron Ultrafast CT Scanner, remains unchanged from the intended use of prior predicate Imatron and other scanners. The Imatron Ultrafast CT Scanner is designed -- as are all similar devices -- to produce cross sectional images (i.e., thin slices) of the human anatomy. In this instance, such images are produced via helical (i.e., continuous volume or dynamic) or stationary (i.e., static) scanning. Imatron's device is -- as are some of the predicate devices -- also intended to be used for clinical situations requiring determination of specific quantitative information, such as the determination of calcium or other materials in bone, tumors, or organs.



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972879

Prescription Use _____
(Per 21 CFR 801.109)