

OCT 7 1999

K993038

510(k) Summary

Date: 9 September 1999

Submitter's Name: Toshiba America Medical Systems, Inc.

Submitter's Address: P.O. Box 2068, 2441 Michelle Drive,
Tustin, CA 92781-2068

Submitter's Contact: Diana Thorson, Regulatory Affairs Specialist, (714)730-5000

Establishment Registration Number: 2020563

Device Proprietary Name: Toshiba RTP9211J-G11, J-Advanced Image Intensifier (I.I.)

Common Name: System, X-Ray, Fluoroscopic, Image Intensified
[Fed. Reg. No. 892.1650, Pro. Code: 90JAA]

Regulatory Class: II (per 21 CFR 892.1650)

Performance Standard: 21 CFR Subchapter J,
Federal Diagnostic X-ray Equipment Standard

Predicate Device(s): Toshiba 6" I.I. System [K771298]

Reason For Submission Modification of cleared device

Description of this Device:

The J-Advanced I.I., Model RTP9211J-G11 is a modification to a previously cleared device, 6" I.I. system [K771298].

Summary of Intended Uses:

The Toshiba J-Advanced I.I. is designed to capture x-ray images on a phosphor, and convert the x-ray pattern into a corresponding light image of a higher energy density. The intended use of this product is commensurate with other products currently in the marketplace.

Technological Characteristics:

This device employs the same technological characteristics as the predicate device. The changes to the device are a result of continuing technological development towards the goals of increasing efficiency and reducing cost. A comparison of the performance characteristics of the new intensifier to the previous models shows nominally improved resolution and contrast specifications. There are no new claims of effectiveness and no new intended uses offered with this new intensifier.

Safety and Effectiveness Concerns:

This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR § 1020.30 and 1020.33, that apply to this device, will be met and reported via a supplement to the initial report for the predicate device. Additionally this system is in conformance with the applicable parts of the IEC-60601 - Medical Device Safety standards.

Substantial Equivalence:

Based upon the above considerations TAMS believes that this device, J-Advanced I.I., Model RTP9211J-G11, is substantially equivalent to the predicate, Toshiba 6" I.I. System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 7 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Diana Thorson
Regulatory Affairs Specialist
Toshiba America Medical Systems, Inc.
2441 Michelle Drive, P.O. Box 2068
Tustin, CA 92781-2068

Re: K993038
J-Advanced Image Intensifier
Model RTP9211J-G11
Dated: September 9, 1999
Received: September 10, 1999
Product Code: 90 JAA
Regulatory Class: II (TWO)
21 CFR 892.1650

Dear Ms. Thorson:

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): _____

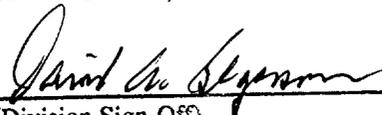
Device Name: J-Advanced I.I., RTP9211J-G11

Indications for Use:

The Toshiba J-Advanced I.I. is designed to capture x-ray images on a phosphor, and convert the x-ray pattern into a corresponding light image of a higher energy density.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K993038

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)