JUN 1 3 2014

K133553
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## 510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

1. **CLASSIFICATION and DEVICE NAME:**

| | |
|---|---|
| **Classification Name:** | **System, X-ray, Fluoroscopic, Image-Intensified** |
| **Regulation Number:** | **21 CFR 892.1650 (Class II)** |
| **Product Code** | **JAA – Image Intensified Fluoroscopic X-ray System** |
| **Trade Proprietary Name:** | **KALARE** |
| **Model Number:** | **DREX-KL80** |

2. **ESTABLISHMENT REGISTRATION:** 2020563

3. **CONTACT PERSON, U.S. AGENT and ADDRESS:**

**Contact Person:**
Charlemagne Chua
Manager, Regulatory Affairs
(714) 669-7896

**U.S. Agent:**
Paul Biggins
Director, Regulatory Affairs
(714) 730-5000

**Establishment Name and Address:**
Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle Drive
Tustin, Ca. 92780

4. **MANUFACTURING SITE**
Toshiba Medical Systems Corporation (TMSC)
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan

5. **Date OF SUBMISSION:**
November 18, 2013

6. **PERFORMANCE STANDARD:**
21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

**7. PREDICATE DEVICE:**
KALARE (DREX-KL80) , K110785

**8. REASON FOR SUBMISSION:**
Modification of a cleared device

**9. SUBMISSION TYPE:**
Traditional 510(k)

**10. DEVICE DESCRIPTION:**

The main function of the KALARE (DREX-KL80) is to perform fluoroscopy/radiography of the examinations of the gastrointestinal tract examination, support for endoscopy, non-vascular contrast study, general abdominal radiography and general skeletal radiography. Using fluorescent scintillation effects of X-rays that have passed through the patient's body, image information is obtained for medical diagnosis and treatment.

**11. SUMMARY OF INTENDED USES:**

a. Intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic examinations, including general R&F and pediatric examinations
b. Intended for use by a qualified/trained doctor or technologist on both adult and pediatric subjects taking diagnostic radiographic and fluoroscopic exposures of the whole body, skull, spinal column, chest, abdomen, extremities and other body parts. Applications can be performed with the patient sitting, standing, or lying in prone or supine position.

**12. SUMMARY OF CHANGE(S)**

a. Addition of a previously cleared FPD.

**13. SUBSTANTIAL EQUIVALENCE:**
This device is substantially equivalent to the KALARE, K110785, marketed by Toshiba America Medical Systems. KALARE includes modifications to the cleared device which adds FPD (in addition to I.I). The basic system configuration, method of operation, base software and manufacturing process remain unchanged from the cleared device.

**14. SAFETY:**
The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1 standards, its collateral standards and particular standards; IEC 60601-2-7, IEC60601-2-28 and IEC 60601-2-32. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via product report.

## 15. TESTING

Testing of the modified system was conducted in accordance with the applicable standards published by the International Electromechanical Commission (IEC) for Medical Devices and XR Systems. Bench testing was done to confirm that the installation of the detector met the stated specifications of the component manufacturer. Additional testing was done to compare the performance between the predicate device and the modified device that included testing directed at image quality, artifacts and motion/dynamic capabilities. The conclusion of this testing demonstrated that substantial equivalence to the predicate device could be proven without the use of clinical images. Additionally, in support of this conclusion the detector component has been the subject of other 510k Premarket Notifications where the clinical aspects of the component have been addressed.

## 16. CONCLUSION

The modifications incorporated into the KALARE, do not change the indications for use or the intended use of the device. Safety and effectiveness have been verified via risk management and the application of design controls to the modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 13, 2014

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K133553
Trade/Device Name: KALARE (DREX-KL80) with FPD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: May 15, 2014
Received: May 16, 2014

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

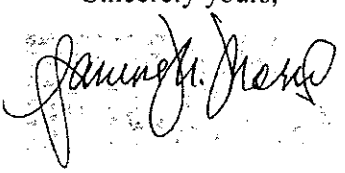
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*

K133553

Device Name
KALARE (DREX-KL80) with FPD

Indications for Use *(Describe)*

1. Intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic examinations, including general R&F and pediatric examinations.

2. Intended for use by a qualified/trained doctor or technologist on both adult and pediatric subjects taking diagnostic radiographic and fluoroscopic exposures of the whole body, skull, spinal column, chest, abdomen, extremities and other body parts. Applications can be performed with the patient sitting, standing, or lying in prone or supine position.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*