Appendix A

510(K) summary
Per title 21 CFR 807.92

CDCR 5020s,UCCR7001,TCCR7001
CR Readers – COMPUTED RADIOGRAPHY IMAGING SYSTEMS

1. SUBMITTER : **CR TECH LTD**
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Haifa 34951
Israel

2. CONTACT PERSON : **David Hashavit**
Regulatory Affairs Manager
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Israel
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3. Submission Date : 08 APRIL 2005

4. Device Name
Trade Names : CDCR5020s
UCCR 7001
TCCR 7001
Common Name : Storage Phosphor reader cassette and cassetteless based

5. Device Classification : Class II per CFR 892.2030
PRODUCT CODE : MQB

6. PREDICATE DEVICES
The CDCR 5020s ,UCCR7001 and TCCR7001 CR READERS devices are substantially equivalent to the following predicate devices with regard to device features and specifications ,as well as intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

CR Tech, Inc.
% Mr. Leonard Frier
Official Correspondent
MET Laboratories, Inc.
914 West Patapsco Avenue
BALTIMORE MD 21230-3432

AUG 23 2013

Re: K051494
Trade/Device Name: Medical Image Digitizer, Models: CDCR 5020s, UCCR 7001 and TCCR 7001
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: September 8, 2005
Received: September 9, 2005

Dear Mr. Frier:

This letter corrects our substantially equivalent letter of September 21, 2005.
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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

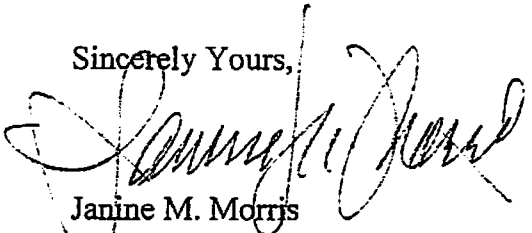
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510K number: **K051494**

Device Name: Medical Image Digitizer

Indications For Use

The CDCR5020s,UCCR7001 and TCCR7001 are intended to be used in radiological practices as laser digitizers for phosphor storage plate. The images are sent for processing to a PC.

1. Model CDCR 5020s
   This device is used on cassette based x-ray systems using the standard Buckey exist on every system.
   After exposing the cassette which includes the phosphor plate ,the plate is digitized and the digital image is transferred to the PC for processing

2. Models UCCR 7001 ,TCCR 7001
   With these two devices the organ or object for x-ray exposure are positioned In the front of the device (near the phosphor plate which is positioned into the device) and after exposure the digitizing process is taking place,then the Digital image is transferred to the PC for processing.
   The only difference in the models are the way of use eather Vertical for Upright or horizontal under the Radiographic Table.

ALL ABOVE MODELS ARE NOT TO BE USED FOR MAMMOGRAPHY

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyman

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

510(k) Number K051494

Prescription Use X or Over-The-Counter Use ____