510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

K103035

Device Name
Proprietary Device Name: Duet DRF

Establishment Name and Registration Number of Submitter

Name: CMT Medical Technologies Ltd.
Registration: 8030112
Submission contact: Shlomi Dines
Hacarmel St. Bld 7/2, POB. 111,
Industrial Park, Yoqneam Ilit 20692, ISRAEL,
Tel:+972-4-8566220 +972-52-4854411, Fax:+972-3-5212202,

MAR 2 9 2011

Device Classification

Product Code:	MQB
Regulation Number:	892.1650
Common Name:	Solid state X-Ray imager
Classification Name:	Image intensified fluoroscopic x-ray system
Regulatory class:	Class II

Reason for 510(k) Submission
Abbreviated 510(k) Submission

Identification of Legally Marketed Equivalent Devices
K080859 DRF 4343

Device Description
The Duet DRF is a Digital Radiography system, featuring an integrated flat panel digital detector (FPD) same as in K080859 DRF 4343, Villa sistemi medicali S.p.A. (this is the 510(k) for the system that incorporate the same flat panel detector and state of the art object-oriented software and connectivity.

Indications for use
The Duet DRF is a digital image acquisition system to be used in conjunction with a solid state detector during radiography or fluoroscopy x-ray examination to capture, digitalize, review images and format images according to DICOM protocol to be sent through network connection.

This device is not intended for mammography use

Safety & Effectiveness
The device has been designed verified and validated complying with 21CFR 820.30 regulations.
Tests data demonstrate that the Duet DRF meets the required specifications.
No adverse affects have been detected.

Substantial Equivalency
It is CMT opinion that the Duet DRF is substantially equivalent in terms of safety and effectiveness to the predicate device.

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

Mr. Shlomi Dines
Director of Quality and Regulatory Affairs
CMT Medical Technologies, Ltd.
Hacarmel St. Bld 7/2, PO Box 111, Industrial Park
YOQNEAM ILIT 20692
ISRAEL

AUG 20 2013

Re: K103038
Trade/Device Name: Duet DRF
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA and MQB
Dated: December 14, 2011
Received: February 22, 2011

Dear Mr. Dines:

This letter corrects our substantially equivalent letter of March 29, 2011.

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

510(k) Number (if known): K103038

Device Name: Duet DRF

Indications For Use: The Duet DRF is a digital image acquisition system to be used in conjunction with a solid state detector during radiography or fluoroscopy x-ray examination to capture, digitalize, review images and format images according to DICOM protocol to be sent through network connection.

This device is not intended for mammography use

Prescription Use: YES (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use: NO (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103038