



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

Solutions for tomorrow AB
% Mr. Martin Yngvesson
COO
Saxagardsv. 4
Vackelsang, 36251 Kronoberg
SWEDEN

July 17, 2017

Re: K170607
Trade/Device Name: !M1
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: June 19, 2017
Received: June 19, 2017

Dear Mr. Yngvesson:

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,

 For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170607

Device Name

!M1

Indications for Use (Describe)

The device is designed to perform general radiography x-ray examinations on all pediatric and all adult patients, in all patient treatment areas.

Treatment areas are defined as professional health care facility environments where operators with medical training are continually present during patients' examinations.

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)


CONTINUE ON A SEPARATE PAGE IF NEEDED.

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”510(k) Summary”

510(k) Owner Name: Solutions for tomorrow AB

510(k) Owner Address: Saxagårdsvägen 4
362 51 Väckelsång

510(k) Owner Phone: +46-(0)10 4564500

Contact Person & Info: Mattias Guldstrand
CEO
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Date Summary Prepared: January 31, 2017

Device Trade Name: !M1

Device Common Name: mobile x-ray system

Classification Name: System, X-ray, Mobile

Regulation Number: 21 CFR 892.1720

Device Class: Class II

Product Code: IZL



Predicate Device:	Carestream DRX-Revolution
Manufactured by:	Carestream Health, Inc.
510(k) Number:	K120062 (January 5, 2011)
Device Trade Name:	DRX-Revolution Mobile X-ray System
Device Common Name:	mobile x-ray system
Classification Name:	System, X-ray, Mobile
Regulation Number:	21 CFR 892.1720
Device Class:	Class II
Product Code:	IZL

Device Description

The ModelOne mobile X-ray system is a diagnostic mobile x-ray system utilizing digital radiography technology. The device consists of a self-contained x-ray generator, image receptor(s), imaging display and software for acquiring medical diagnostic images both inside and outside of a standard stationary x-ray room. The ModelOne system incorporates a flat-panel(s) detector that can be used wirelessly for exams as in-bed projections. The system is intended to be marketed with two options with flat-panel digital images from Canon and Konica Minolta. The flat-panel digital imagers have been previously cleared with the following:

- K133693 – Digital Radiography CXDI-401C Wireless (Canon)
- K131106 – Digital Radiography CXDI-701C Wireless (Canon)
 - Digital Radiography CXDI-701G Wireless
 - Digital Radiography CXDI-801C Wireless
 - Digital Radiography CXDI-801G Wireless
- K102349 – AeroDR SYSTEM (Konica Minolta)
- K113248 – AeroDR SYSTEM with P-21 (Konica Minolta)
- K130936 – AeroDR SYSTEM with P-31 (Konica Minolta)
- K141271 – AeroDR SYSTEM 2 (Konica Minolta)
- K162504 - SKR 3000 (Konica Minolta)

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Indications for Use / Intended Use:

The Indications for Use for the device, as described in its labeling, are:

“The device is designed to perform general radiography X-ray examinations on all paediatric and all adult patients, in all patient treatment areas”.

Note

The patient subpopulations are identified by weight. The equipment settings for routinely performed examinations for those populations can be found in User Manual, section Exposure parameters. However, the image post-processing is defined in protocols from Konica Minolta and Canon image software that have been already approved by FDA.

Comparison of Technological Characteristics

The !M1 Mobile X-ray System is substantially equivalent to the predicate device, the DRX-Revolution Mobile X-ray System manufactured by Carestream Health, Inc. The !M1 and DRX-Revolution system both consist of an x-ray generator, x-ray tube, collimator and graphical user interface on an operator console with touch screen monitor. These components are mounted on a motorized cart that is battery powered to enable the device to be moved from location to location. Both systems utilize digital flat panel detector for image capture.

Discussion of Testing

Non-clinical testing

The performance characteristics and operation of !M1 were evaluated in non-clinical testing. Performance tests include the following: usability test, battery performance, driving distance and generator performance test. The usability test includes the acceptance test performed on the customer site and performance test that has been done at the hospital by professional personal. Battery performance tests consists of beginning of life/end of life test. The driving distance test was performed to verify maximum distance of driving from full to empty battery. The aim of generator performance test was to compare the time of exposure of !M1 and its competitors.

Integration test was performed on the previously cleared flat-panel digital imagers in order to demonstrate that all components of the device function in a reproductive way according to the design specifications.



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Performance tests confirm that the device is as effective and performs as well as or better than the predicate device. The software risk is classified as moderate level of concern device according to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Technological differences do not raise questions of safety and the device is as safe as legally marketed DRX-Revolution by Carestream.

Clinical testing

No clinical testing was performed on the subject device, and performance testing listed in the “Non-Clinical Testing” section was sufficient to demonstrate substantial equivalence.

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