K132041

JUL 3 1 2013

Section 9

Attachment 5

510(k) Summary

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1. 510(k) Owner:

Metabiomed, Inc.
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Horsham, PA 19044
USA
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Fax: 267-282-5899
Email: metabiomed@gmail.com

2. Company Contact:
   Title:

Ian Yun
Sales Director

3. 510(k) Preparer:

Blix Winston
ACMD Consulting, LLC.
2600 Mullinix Mill Road
Mt. Airy, MD 21771
USA
Ph: 301-607-9185
Email: fblixwinston@aol.com

4. Date of Submission

June 25, 2013

5. Device Name and Classification:

Trade name – REXTAR X
Common name - Portable X-Ray System
Classification name - Extraoral source x-ray system

6. Predicate Devices:

Manufacturer :	Poskom Co. Ltd.
Device :	Rextar LCD
510(k) Number :	K122016 (Decision Date - 03/01/2013)

7. Classifications Names & Citations:
   21CFR 872.1800, EHD - Extraoral source x-ray system, Class 2

8. Compliance with performance standards
   All components to which the standard applies are certified to conform to diagnostic equipment standards, 21 CFR 1020.30 and 1020.31.

9. Device Description:

   a. General:
   The REXTAR X consists of an X-ray tube, X-Ray tube assembly, X-Ray Controller built into a hand held camera-like device. The Rextar model contains additional accessories.

   b. Outline:

   The REXTAR X is an extraoral source x-ray system with a DC-powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source a, X-ray camera, is located outside the mouth. This generic type of device may include patient and equipment supports and component parts.

   c. Features:

   REXTAR X has the following qualities:

   - High Frequency X-ray Generator (70kV-2mA Fixed)
   - High Quality Toshiba Tube used (Tube Focal Spot (0.4mm))
   - Target Angle 12°
   - Easy to Move
   - Eliminates the need for multiple X-Ray units in doctor's office
   - Efficient to use
   - Compact Size & Light Weight Design for Ultimate Portability
   - Long Battery Life - Hundreds of images can be obtained from one time charge
   - Diverse Applications (Field Hospital, Emergency, Forensic Science, Operation Room)
   - Can use conventional film or digital sensors to obtain images
   - Images from digital sensors are displayed on a computer that is not included as a part of the camera for the Rextar X

   d. Operating principle:

   Operating principle is that X-ray generated by high voltage electricity into X-ray tube, which penetrates hand, tooth and jaw, and makes X-ray images on receptor (Chemical Film or Digital Sensor).

10. Indications for use:

REXTAR X is to be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.

11. Substantial equivalence:

The REXTAR devices have been tested to demonstrate substantial equivalence with the predicate devices. A comparison of features is included below.

Comparison Table: REXTAR, REXTAR LCD and the Predicate Devices

Parameter	Rextar X	Rextar LCD
510(k)	Submitted for marketing clearance	K122016
Intended Use	To be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.	To be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.
Indications	X-ray system designed to provide images of the patients undergoing dental procedures. Clinical uses include Bite wing, periapical, occlusal and panoramic images.	X-ray system designed to provide images of the patients undergoing dental procedures. Clinical uses include Bite wing, periapical, occlusal and panoramic images.
Dentist/dental assistant Involvement	Supervision	Supervision
Labeling	Submitted	Submitted
X-ray Generator	High-Frequency	High-Frequency
Tube Power	70kV /2mA	70kV /2mA
Tube Type	Stationary	Stationary
Tube Focal Spot	0.4mm	0.4mm
Target Angle	12°	12°
Exposure Time	0.01 ~ 1.30 (sec) (43 steps)	0.01 ~ 1.3 (sec) (43 Steps)
Power Requirement	DC 11.1 V	DC 11.1 V
Picture Quality	Good	Good
Battery Type	Rechargeable	Rechargeable

Parameter	Rextar X	Rextar LCD
Display	LCD Panel Display (3.5 Inch, BTN LCD, 1/4Duty, 1/3BIAS)	LCD Panel Display (4 Digits, 0.5 Inch Character Height)
Size	146×155×139mm	404× 234× 198mm
Weight (kg)	2	1.88

12. Standards:

    The portable x-ray system, REXTAR X will comply with applicable requirements of the Underwriters Laboratories Standard for Safety-UL/IEC 60601-1, IEC 60601-2-7, IEC 60601-2-28 and IEC 60601-2-32.
    EMC testing was conducted by (EMC Compliance Co., Ltd. in accordance with Standard EN/IEC 60601-1-2). All test results were satisfactory.

13. Conclusion: Based on comparison with the predicate devices and the results of testing Metabiomed believes its REXTAR and REXTAR LCD devices are substantially equivalent

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

July 31, 2013

Meta Biomed, Incorporated
C/O Mr. Blix Winston
ACMD Consulting, Limited Liability Company
2600 Mullinix Mill Road
MT AIRY MD 21771

Re: K132041
Trade/Device Name: Rextar X
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: II
Product Code: EHD
Dated: June 24, 2013
Received: July 2, 2013

Dear Mr. Winston:

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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K132041

Device Name: REXTAR X

Indications for Use:

REXTAR X is a portable X-ray system to be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.

Prescription Use Yes **AND/OR**

(Part 21 CFR 810 Subpart D) **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.07.30 14:51:48 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K132041