K133684
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JAN 13 2014

X-ray Attenuating Cream

Section 5 – 510(k) Summary

1 GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k)

BLOXR Corporation
960 Levoy Drive
Salt Lake City, Utah 84123

1.2 Official Correspondent

Rai Chowdhary
Vice President of Operations and Engineering
960 Levoy Drive
Salt Lake City, Utah 84123
Telephone: (512) 560-8326
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E-mail: rchowdhary@bloxr.com

1.3 Date of Preparation

Nov 25 2013

2 NAME OF THE DEVICE

2.1 Trade/Proprietary Name

ULTRABLOX

2.2 Common/Usual Name

X-ray Attenuating Cream, or Cream for x-ray attenuation

2.3 Classification Information

Classification Name: Cream for x-ray attenuation
Classification Regulation: 21 CFR § 892.6510
Class: II
Product Code: PDK
Panel: Radiology

3 PREDICATE DEVICES

This device is the same X-ray Attenuating Cream that was cleared under the De Novo 510(k) K 123422, and classified as a Class II medical device. The device was earlier cleared for use with natural rubber latex surgical gloves only.

4 DESCRIPTION OF THE DEVICE

The X-ray Attenuation Cream is a sterile cream intended for use as a radiation shield. It is intended to be applied to the user's hand before donning gloves, or it may be applied on a glove on the hand, followed by donning a second glove. The X-ray Attenuation Cream is intended for use during medical procedures in which hands are necessarily exposed to radiation to offer some degree of protection from radiation exposure in the diagnostic imaging range of up to 130 KVp. This may include surgical procedures that require the use of fluoroscopy or radiography or other procedures. The X-ray Attenuation Cream is not intended to be used in the primary beam or the transmitted beam and should not be used in lieu of a Radiographic Procedure Glove, which is used in radiography for those studies requiring the physician's hand or forearm be in the direct path of the primary x-ray beam.

5 INDICATIONS FOR USE AND INTENDED USE

The X-ray Attenuating Cream has the same intended use, and indications for use as before, with the addition of indications for use with poly-isoprene surgeon's gloves as below:

> *The X-ray Attenuating Cream is intended for use as a radiation shield. It is intended to be applied to the user's hand before donning gloves, or it may be applied on a glove on the hand, followed by donning a second glove. The X-ray Attenuating Cream is intended to be used during medical procedures where hands are necessarily exposed to radiation to offer some degree of protection from radiation exposure in the diagnostic imaging range of up to 130 kVp. This may include surgical procedures that require the use of fluoroscopy or radiography or other procedures.*

NOTE: For use with natural rubber latex and latex-free poly-isoprene Surgeon's Gloves only.

6 TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

The X-ray Attenuating Cream is the same device that was cleared under De Novo 510(k) K123422. There is no change to packaging and sterilization. Since it is the same device, it has the same radiation attenuation and bio compatibility characteristics. The X-ray Attenuating Cream is now compatible for use with natural rubber latex, and latex-free poly-isoprene Surgeon's Gloves. The table below provides for a summary of what has changed in the X-ray Attenuating Cream.

X-ray Attenuating Cream vs. predicate X-ray Attenuating Cream

Characteristic	Change from Predicate (from / to)
Composition	None
Radiation attenuation	None
Bio-compatibility	None
Compatibility with gloves	Yes (compatible with natural rubber latex surgeons gloves / compatible with natural rubber latex surgeons gloves, and latex-free poly-isoprene surgeon's gloves)
Packaging and sterilization	None
Type of procedures used for	None
Intended use	… not intended to be used in or adjacent to the primary beam…/ …not intended to be used in the primary beam…

7 PERFORMANCE TESTING

The performance data presented in this 510(k) application demonstrate the X-ray Attenuating Cream can be used with latex-free poly-isoprene surgeon's gloves in addition to the previously cleared use with natural rubber latex surgeon's gloves.

8 CONCLUSIONS

This 510(k) submission provides the evidence that the X-ray Attenuating Cream is substantially equivalent to the device cleared under 510(k) K 123422.

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

January 13, 2014

BLOXR Corporation
% Mr. Prataprai (Rai) Chowdhary
VP Operations and Engineering
960 Levoy Drive
SALT LAKE CITY UT 84123

Re: K133684
Trade/Device Name: Ultrablox
Regulation Number: 21 CFR 892.6510
Regulation Name: Cream for X-ray Attenuation
Regulatory Class: II
Product Code: PDK
Dated: November 26, 2013
Received: December 2, 2013

Dear Mr. Chowdhary:

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,

for

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133684

Device Name
UltraBLOX X-ray Attenuating Cream

Indications for Use *(Describe)*
The X-ray Attenuating Cream has the same intended use, and indications for use as the device cleared under 510(k) K123422, with the addition of indications for use with poly-isoprene surgeon's gloves as below:

Device Name: X-ray Attenuating Cream

Indications for use:
The UltraBLOX X-ray Attenuating Cream is intended for use as a radiation shield. It is intended to be applied to the user's hand before donning gloves, or it may be applied on a glove on the hand, followed by donning a second glove. The UltraBLOX X-ray Attenuating Cream is intended to be used during medical procedures where hands are necessarily exposed to radiation to offer some degree of protection from radiation exposure in the diagnostic imaging range of up to 130 kVp. This may include surgical procedures that require the use of fluoroscopy or radiography or other procedures.
NOTE: For use with natural rubber latex and latex-free poly-isoprene Surgeon's Gloves only.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."