



May 9, 2013

Mr. Prataprai (Rai) Chowdhary
VP - Operations & Engineering
BloXR Corporation
960 West Levoy Drive, Suite 100
Salt Lake City, UT 84123

Re: K123422 – Order Granting the Request for De Novo Classification
X-ray Attenuating Cream
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 892.6510
Regulation Name: Cream for x-ray attenuation
Regulatory Classification: Class II
Product Code: PDK
Dated: February 1, 2013
Received: February 4, 2013

Dear Mr. Chowdhary:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the X-ray Attenuating Cream, a prescription device under 21 CFR Part 801.109, that 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. X-ray Attenuating cream is not intended to be used in or adjacent to the primary x-ray 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. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the X-ray Attenuating Cream, and substantially equivalent devices of this generic type, into class II under the generic name, cream for x-ray attenuation.

FDA identifies this generic type of device as: cream for x-ray attenuation. Cream for x-ray attenuation 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. Cream for x-ray attenuation is intended to be used 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. Cream for x-ray attenuation is not intended to be used in or adjacent to the primary x-ray 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.

Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On February 4, 2013, FDA received your *de novo* requesting classification of the X-ray Attenuating Cream into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the X-ray Attenuating Cream into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the X-ray Attenuating Cream can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The X-ray Attenuating Cream is indicated 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. X-ray Attenuating cream is not intended to be used in or adjacent to the primary x-ray 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.

FDA has identified the risks of cream for x-ray attenuation as:

1. *Adverse tissue reaction to health care professionals and patients as a result of direct contact to the skin.* Health care professionals may apply the cream directly to their hands for use. Patients may be exposed to the cream as a result of glove failure due to incompatibility with the cream formulation weakening the mechanical characteristics of the surgical gloves. The adverse tissue reaction would be due to toxic, irritating, or sensitizing agents present in the cream formulation.
2. *Infection risk to patient as a result of patient contact with contaminated/compromised cream due to glove failure.* Glove failure could occur due to incompatibility with the cream formulation weakening the mechanical characteristics of the surgical gloves. Infection to the patient could occur as a result of non-sterile cream, contaminated/compromised cream and loss of the sterile boundary due to glove failure.

3. *Radiation exposure to health care professionals due to lack of radiation attenuation. Lack of radiation can occur due to inadequate or inconsistent cream formulation. The radiation attenuating agent in the cream may not be present in high enough concentration or is not appropriate to provide the amount of protection needed.*
4. *Radiation exposure to health care professional during actual use (lack of effectiveness). Lack of continuous protection during actual use can result from poor cream composition such that the cream will absorb, crack, flake off, etc. during use in a clinical setting.*
5. *Radiation exposure to health care professionals due to inconsistent device application. Radiation exposure can result due to inadequate instructions describing how to apply the cream and how often to reapply the cream to ensure that the hands are completely covered and covered with enough cream to provide the amount radiation protection stated in the labeling.*

Special controls are necessary to address the risks posed by this device and to provide a reasonable assurance of safety and effectiveness. In addition to the general controls of the FD&C Act, cream for x-ray attenuation is subject to the following special controls:

1. The premarket notification submission must include results from safety and effectiveness testing. The results from safety and effectiveness testing must include:
 - a. Biocompatibility data consistent with the intended use for the device;
 - b. Sterilization, packaging, and expiration date testing; and,
 - c. Nonclinical and/or clinical performance testing representative of “as use” conditions demonstrating:
 - i. compatibility to the type(s) of surgical glove (i.e., latex, nitrile, vinyl, etc.) to be used with the device;
 - ii. attenuation performance; and,
 - iii. proper application of the device.
2. Labeling must include:
 - a. A statement that the device is sterile and an expiration date.
 - b. A warning statement placed in a black box prominently placed in all labeling material for these devices. That warning statement must read:

The device is **not** intended to be used in or adjacent to the primary X-ray beam or 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.

- c. The methods and results from nonclinical and/or clinical performance testing representative of “as use” conditions demonstrating the amount of attenuation the device provides to the end user at 60, 80, 100, and 120 kVp.
- d. Validated instructions for use for device application and state how often the device must be removed and reapplied for effective shielding.
- e. Identification of the type(s) of surgical glove (i.e., latex, nitrile, vinyl, etc.) that are compatible for use with the device.

Table – Identified Potential Risks and Required Mitigation Measures

Identified Potential Risks	Required Mitigation Measures
Adverse tissue reaction to health care professionals and patients as a result of direct contact to the skin.	<ul style="list-style-type: none"> (1) Biocompatibility testing (2) Surgical glove compatibility performance testing (3) Identification of compatible surgical gloves in labeling
Infection risk to patient as a result of patient contact with contaminated cream due to glove failure and the cream flaking off onto the patient.	<ul style="list-style-type: none"> (1) Sterilization, packaging, and expiration date testing. (2) Sterile device and expiration date statement in labeling (3) Surgical glove compatibility performance testing (4) Identification of compatible surgical gloves in labeling
Radiation exposure to health care professionals due to lack of radiation attenuation because of cream formulation. The radiation attenuating agent in the cream may not be present in high enough concentration or is not appropriate to provide the amount of protection needed.	<ul style="list-style-type: none"> (1) Black box warning in labeling (2) Attenuation information in labeling (3) Surgical glove compatibility performance testing (4) Attenuation performance testing (5) Application performance testing
Radiation exposure to health care professional during actual use (lack of effectiveness). Lack of continuous protection during actual use can result from poor cream composition such that the cream will absorb, crack, flake off, etc. during use in a clinical setting.	<ul style="list-style-type: none"> (1) Black box warning in labeling (2) Attenuation information in labeling (3) Surgical glove compatibility performance testing (4) Attenuation performance testing (5) Application performance testing (6) Validated device application instructions for effective shielding in labeling

<p>Radiation exposure to health care professionals due to inconsistent device application. Radiation exposure can result due to inadequate instructions describing how to apply the cream to ensure that the hands are completely covered and covered with enough cream to provide the amount of radiation protection stated in the labeling.</p>	<p>(1) Validated device application instructions for effective shielding in labeling</p>
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Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the cream for x-ray attenuation they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may market your device, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Jeffrey J. Ballyns at (301) 796-6105.

Sincerely yours,



Janine M. Morris
Director, Division of Radiological Health
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and
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