MEDICAL SOLUTION TECNOLOGY

La semplice ed efficace protezione per le mani!!

- ✓ Riduce l'esposizione alle radiazioni diffuse fino all'85%
- ✓ Mantiene inalterato l'uso delle dita ed il tatto
- ✓ Bio-compatibile ed atossica
- ✓ Facile e veloce applicazione
- ✓ Certificato FDA e CE

Crema attenuatrice ULTRABLOX

Facile da Applicare.
La praticità e semplicità d'uso, rendono la Crema Attenuatrice **ULTRABLOX** uno strumento affidabile e di uso continuativo nelle procedure di preparazione dell'operatore.
ULTRABLOX può essere utilizzata in due modi:

METODO A SINGOLO GUANTO

Aprire il tubo e spremere la crema attenuatrice in una mano

Diffondere la crema su i due lati di entrambe le mani, facendo attenzione a spalmarla uniformemente e completamente su ogni lato e tra ogni dito. Utilizzare una quantità di crema sufficiente in modo che entrambe le mani risultino completamente ricoperte con uno strato sottile di crema

Indossare i guanti chirurgici facendo attenzione a incapsulare la crema tra il guanto e la mano

Lavare le mani con un sapone abrasivo o una barretta abrasiva utilizzando la vostra usuale tecnica post-operatoria

METODO A DOPPIO GUANTO

Indossare il primo paio di guanti in lattice

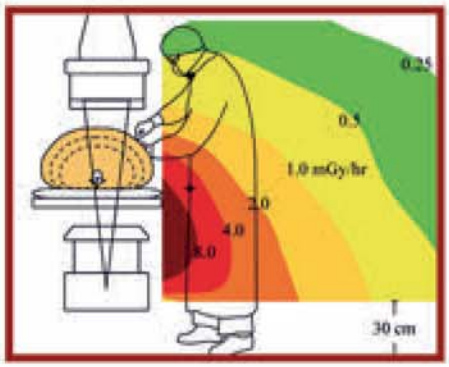
Aprire il tubo e spremere la crema attenuatrice sui guanti

Diffondere la crema su i due lati di entrambe le mani, facendo attenzione a spalmarla uniformemente e completamente su ogni lato e tra ogni dito. Utilizzare una quantità di crema sufficiente in modo che entrambe le mani risultino completamente ricoperte con uno strato sottile di crema

Indossare i guanti chirurgici facendo attenzione a incapsulare la crema tra i due guanti

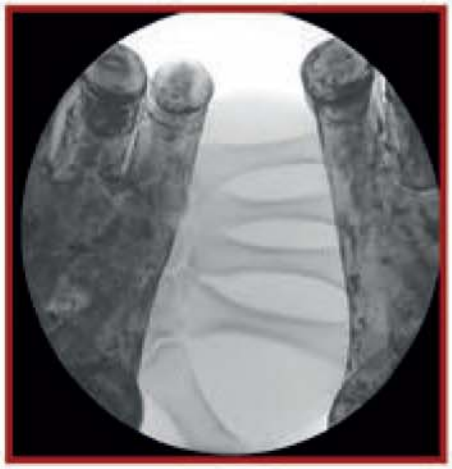
Togliere entrambi i guanti in una unica operazione

La protezione delle mani dalle radiazioni ionizzanti finora è stata frequentemente trascurata in quanto l'unico sistema conosciuto era l'utilizzo di guanti in piombo che, a causa del peso e dello spessore non consentono all'operatore la sensibilità tattile, indispensabile per gli operatori.



Ora c'è una soluzione migliore.

La crema **ULTRABLOX** protegge le mani, mantenendo inalterate flessibilità e tatto.



La crema è morbida e facile da applicare e consente all'operatore di fornire assistenza ai pazienti, riducendo in modo significativo la dose di radiazioni alle mani.

Desquamazione della pelle, perdita dei capelli, e scolorimento dei letti ungueali sono solo alcune delle conseguenze di una esposizione prolungata alle radiazioni ionizzanti.

Ridurre l'esposizione dannosa per le mani durante le procedure significa Essere efficace ed essere in buona salute.

ULTRABLOX è un dispostitivo di protezione individuale (DPI) certificato: FDA 510(k) CE 0120 DIRECTIVE 89/686/EEC

MEDICAL SOLUTION TECNOLOGY

Via Conte Giusso 2/H 70125 Bari
Tel. 080 8769507 - Fax 080 2220241
P.IVA 07660740726
Massimo Gabriele
349 2386210

Certificate US13/82956

The management system of

BLOXR Solutions, LLC.

960 West Levoy Drive, Suite 100,
Salt Lake City, UT, 84123, United States

has been assessed and certified as meeting the requirements of

Directive 89/686/EEC

Article 11B

For the following activities

Manufacture of Lead free radiation Attenuation aprons, vests, skirts, mitts, thyroid collars and caps and Sterile Xray Attenuating cream (to be used with either one of two pairs of compatible natural latex surgeon's gloves only.

Note: All products marked CE0120 should have a valid E.C. Type Examination Certificate issued under Article 10.

This certificate is valid from 9 April 2015 until 21 August 2016
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 June 2016
Issue 6. Certified since 21 August 2013

Authorised by

SGS United Kingdom Limited, Notified Body 0120
Unit 202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 **f** +44 (0)1934 522137 www.sgs.com

SGS CE 02B 0311

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.

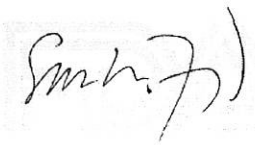
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

1 Identification of Product and Company:

Product name: UltraBLOX™, X-ray Attenuating Cream

Product Code: 100036

Manufacturer/Supplier:

BLOXR Corporation
960 West Levoy Drive
Salt Lake City, UT 84123
Phone: (801) 590-9880

Web Site: www.bloxr.com

Information Department: Medical Products Division
Emergency information: During normal hours: (801) 590-9880.
USA: Chemtrec (800) 262-8200

2 Composition/Data on components:

Physical State at Room Temperature: **Cream**
Chemical characterization:

Description:	Bismuth Oxide	5-90%
	Water	1-10%
	Humectants	1-11%
	Emollients	1-10%
	Emulsifier	1-5%
	Preservative	0-1%
	Stabilizer	0-1%
	Thickener	0-1%

Identification number(s): None

3 Hazards identification

Eyes: May cause irritation.
Skin: Does not pose a potential of skin irritation and sensitization.
Inhalation: No known effect.

Information pertaining to particular dangers for man and environment
Classification system
HMIS ratings (scale 0-4)
(Hazardous Materials Identification System)

HEALTH	1
FIRE	1
REACTIVITY	0

GHS label elements
Warning
Health (acute effects) = 1
Flammability = 1
Reactivity = 0
3.2/2 – No skin irritation or sensitization potential
3.3/2A – May cause eye irritation.
3.8/3 – No known effect.

Prevention: Avoid contact with eyes.
Response:
INHALATION: None under normal use.
EYE CONTACT: Rinse thoroughly with plenty of water, also under eyelids. If irritation persists, call a physician.
SKIN CONTACT: None under normal use.
INGESTION: Rinse mouth with water and afterwards drink plenty of water.
Storage:
Store in a well-ventilated place. Keep container tightly closed.
Handle in accordance with good safety practice.
Disposal:
Dispose of contents/container in accordance with local/regional/national/international regulations.

4 First aid measures

Inhalation
None under normal use.
Eye contact
Rinse thoroughly with plenty of water, also under eyelids. If irritation persists, call a physician.

5 Fire-fighting measures

Suitable extinguishing agents
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special hazards caused by the material, its products of combustion or resulting gases:
In case of fire, the following can be released:
Oxides of Carbon
Metal oxide fume

Protective equipment:
Wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH approved or equivalent.
Wear full protective gear.

6 Accidental release measures

Person-related safety precautions:
Avoid contact with eyes.
Measures for environmental protection: Follow local/regional/ national/international regulations as applicable for release to the environment.
Measures for cleaning/collecting: Prevent leakage or spillage if safe to do so. Keep in suitable containers for disposal.
Additional information:
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

***Handling Information for safe handling*:** Store in cool, dry place in tightly closed containers.
Information about protection against explosions and fires: The product is not flammable
Storage Requirements to be met by storerooms and receptacles: No special requirements; avoid exposure to temperatures in excess of 40^0C.
Further information about storage conditions: Keep container tightly sealed. Store in cool, dry conditions

in well-sealed containers.

8 Exposure controls and personal protection

Additional information about design of technical systems: Not required.

***Components with limit values that require monitoring at the workplace*:** Not required.
Additional information: No data available.
Personal protective equipment
General protective and hygienic measures: The usual precautionary measures for handling chemicals should be followed. Keep away from foodstuffs, beverages and feed. Remove all soiled and contaminated clothing immediately. Wash hands before breaks and at the end of work.
Breathing equipment: None required.
Protection of hands: None required.
Eye protection: None required.
Body protection: Protective work clothing.

9 Physical and chemical properties:

General Information
Form: Cream ***Color:*** Yellow / Green ***Odor:*** Odorless
Change in condition
Melting point/Melting range: >~40°C
Boiling point/Boiling range: Not determined
Sublimation temperature / start: Not determined
Flash point: Not applicable
Ignition temperature: Not determined
Decomposition temperature: Not determined
Danger of explosion: Product does not present an explosion hazard.
Explosion limits:
Lower: Not determined ***Upper:*** Not determined
Vapor pressure: Not determined
Density at 20°C (68°F): 2.0 to 5.2 g/cm3
Solubility in / Miscibility with Water: Insoluble

10 Stability and reactivity

Thermal decomposition / conditions to be avoided:
No decomposition expected under normal use.
Materials to be avoided: Oxidizing agents
Dangerous reactions: No dangerous reactions known
Dangerous products of decomposition: Metal oxide fume

11 Toxicological information

Acute toxicity:
LD/LC50 values that are relevant for classification:
Oral LD50 5000 mg/kg (rat)
Primary irritant effect:
On the skin: None expected under normal use. May be irritating to eyes.
Sensitization: *No sensitizing effects known.*
Subacute to chronic toxicity: Product is safe for its intended use based on the formulation, testing results, and the history of use. No known subacute or chronic toxicity effects under normal use. Bismuth compounds are often poorly absorbed. Should absorption occur, however, exposure may cause loss of

appetite, headache, skin rash, exodermatitis, kidney injury and jaundice. Repeated or prolonged exposure may cause a bismuth line or black spots on the gums, foul breath and salivation.

12 Ecological information:

General notes:

The product is neither toxic nor contains any hazardous ingredients. Release of the product to the environment should be done in full compliance with local governmental permits

13 Disposal considerations

Product

Recommendation; Consult state, local or national regulations to ensure proper disposal.

Uncleaned packagings

Recommendation: Disposal must be done in full compliance with applicable local/regional/ national/international regulations.

14 Transport information

Not regulated. Prevent exposure to temperatures in excess of 40^0C as much as possible

Transport/Additional information: Not dangerous according to the above specifications.

DOT regulations: Hazard class: None
Land transport ADR/RID (cross-border) ADR/RID class: None
Maritime transport IMDG: IMDG Class: None
Air transport ICAO-TI and IATA-DGR: ICAO/IATA Class: None

15 Regulations

Product related hazard information

Hazard symbols:

Xi Irritant

Risk phrases:

36/37/38 Irritating to eyes.

Safety phrases:

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
37 Wear suitable gloves.

National regulations

All components of this product are listed in the U.S. Environmental Protection Agency Toxic Substances Control Act Chemical substance Inventory. All components of this product are listed on the Canadian Domestic Substances List (DSL).

Information about limitation of use: For use only by technically qualified individuals.

16 Other information:

Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Material Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.