K121897

JUL 27 2012

CardinalHealth

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

PROTEXIS™ LATEX BASIC, STERILE LATEX POWDER-FREE SURGICAL GLOVES WITH PROTEIN CONTENT LABEL CLAIM OF 50µg/dm² OR LESS (CREAM)

(A summary of safety and effectiveness information in accordance with the requirements of 21 CFR 807.92)

Applicant: Cardinal Health
1430 Waukegan Road
McGaw Park, IL 60085

Establishment Registration Number: 1423537

Regulatory Affairs Contact: Tatyana Bogdan, RAC
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Summary Prepared: June 14, 2012

Trade Name: Protexis™ Latex Basic, Sterile Latex Powder-Free Surgical Glove with Protein Content Label Claim of 50µg/dm² or less (Cream)

Common Name: Surgeon's Gloves

Classification Name: Surgeon's Gloves

Classification Panel: General and Plastic Surgery

Regulation: 21 CFR 878.4460

Product Code(s): KGO

Legally marketed device(s) to which equivalence: Protexis™ Latex Basic, Sterile Latex Powder-Free Surgical Gloves with Protein Content Label Claim of 50µg/dm² or less (Tan) (510(k) K120934, product code KGO)

Reason for 510(k) Submission: Device modification to remove colorant from glove formulation.

Device Description: The proposed device is a disposable device intended for over the counter use and is provided powder-free and sterile. The glove is made with natural rubber latex and is cream in color. The glove is manufactured using molds that feature independent thumb and tapered mechanically locking cuffs to help reduce cuff roll down.

Intended Use: This powder-free surgeon's glove is a disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

Summary of the technological characteristics of the device compared to the predicate device		
Characteristic	**Modified Device** Sterile Latex Powder-Free Surgical Gloves with Protein Content Label Claim of 50 µg/dm^2 or less (Cream)	**Original device (Predicate device cleared under K120934)** Sterile Latex Powder-Free Surgical Gloves with Protein Content Label Claim of 50 µg/dm^2 or less (Tan)
Material Composition	Natural Rubber Latex	Natural Rubber Latex
Design	Single Use Sterile Powder-free Hand Specific Independent Thumb Beaded Cuff Lubricated	Single Use Sterile Powder-free Hand Specific Independent Thumb Beaded Cuff Lubricated
Intended Use/ Indications for Use	Powder-Free Surgeon's Glove	Powder-Free Surgeon's Glove
Dimensions & Physical Properties	Meets ASTM D3577	Meets ASTM D3577
Freedom from Holes	AQL meets 21CFR 800.20 & ASTM D3577 requirements	AQL meets 21CFR 800.20 & ASTM D3577 requirements
Powder Residual	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577
Protein Contents	Contains less than 50 µg/dm^2 of total water extractable protein per glove as tested per ASTM D5712	Contains less than 50 µg/dm^2 of total water extractable protein per glove as tested per ASTM D5712

PERFORMANCE DATA		
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE*		
Performance Test Summary-New Device		
Characteristic	Standard/Test/FDA Guidance	Results Summary
Biocompatibility: Primary Skin Irritation Guinea Pig Maximization **Physical Characteristics**:	 ISO 10993-10 ISO 10993-10	 Meet requirements Meet requirements

Dimensions	ASTM D3577	Meet requirements
Physical Properties	ASTM D3577	Meet requirements for rubber surgical gloves
Freedom from Holes	21 CFR 800.20 & ASTM D3577	Tested in accordance with ASTM D5151 with acceptable results
Powder Residual	ASTM D3577 tested using ASTM standard D6124	Gloves meet powder level requirements for "Powder-Free" designation per ASTM D3577. Results generated values < 2mg of residual powder per glove.
Protein Content	ASTM D5712, FDA Medical Glove Guidance Manual	Gloves yielded the results of less than 50 $\mu g/dm^2$ of total water extractable protein per glove

Comparative Performance Information Summary

Characteristic	Requirement	Modified Device	Original Device
Biocompatibility:	ISO 10993-1	Meets requirements	Meets requirements
Primary Skin Irritation	ISO 10993-10	Meets requirements	Meets requirements
Guinea Pig Maximization	ISO 10993-10	Meets requirements	Meets requirements
Dimensions	ASTM D3577	Meets requirements	Meets requirements
Physical Properties	ASTM D3577	Meets requirements	Meets requirements
Freedom from Holes	21CFR800.20, ASTM D3577	Meets requirements	Meets requirements
Powder Residual	ASTM D3577	Meets requirements	Meets requirements
Protein Content	ASTM D5712	Meets requirements	Meets requirements

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical data is not required.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

Non-clinical data demonstrates that Protexis™ Latex Basic, Sterile Latex Powder-Free Surgical Gloves with Protein Content Label Claim of less than 50 $\mu g/dm^2$ (Cream) meet the technological characteristics of ASTM D3577 standard, and are as safe, as effective, and performs as well as the legally marketed predicate devices identified in this summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2012

Ms. Tatyana Bogdan-Curvin
Regulatory Affairs Manager
Cardinal Health, Incorporated
1430 Waukegan Road
McGaw Park, Illinois 60085

Re: K121897
Trade/Device Name: Protexis™ Latex Basic, Sterile Latex Powder-Free Surgical Gloves with Protein Content Label Claim of 50 $\mu g/dm^2$ or less (Cream)
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: May 14, 2012
Received: June 29, 2012

Dear Ms. Bogdan-Curvin:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CardinalHealth

Indications for Use

510(k) Number (if known): K121897

Device Name: Protexis™ Latex Basic, Sterile Latex Powder-Free Surgical Gloves with Protein Content Label Claim of 50 µg/dm^2 or less (Cream)

Indications for Use: A powder-free sterile surgeon's glove is a disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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