June 19, 2020

Ansell Healthcare Products LLC
Donald Cronk
Associate Director, Regulatory Affairs - Americas
2301 Robb Drive
Reno, Nevada 89523

Re: K200671

Trade/Device Name: Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Blue Colored Tested for Use with Chemotherapy Drugs
Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Green Colored Tested for Use with Chemotherapy Drugs
Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl
CitrateRegulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO (for pink glove only)
Dated: May 21, 2020
Received: May 22, 2020

Dear Donald Cronk:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CAPT Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200671

Device Name
Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Blue Colored Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Test Chemotherapy drug & Concentration	Average Breakthrough Detection Time (Minutes)
Carmustine (BCNU) - 3.3 mg/ml	17.4
Cyclophosphamide - 20.0 mg/ml	>240
Doxorubicin HCl (Adriamycin) 2.0 mg/ml	>240
Etoposide (Toposar) - 20.0 mg/ml	>240
Fluorouracil (Adrucil) - 50.0 mg/ml	>240
Methotrexate - 25.0 mg/ml	>240
Paclitaxel (Taxol) - 6.0 mg/ml	>240
Thiotepa (THT) - 10.0 mg/ml	67.1
Vincristine Sulfate - 1.0 mg/ml	>240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU) : 17.4 minutes and Thiotepa: 67.1 minutes. Warning: Do not use with Carmustine.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200671

Device Name
Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Green Colored Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Test Chemotherapy drug & Concentration	Average Breakthrough Detection Time (Minutes)
Carmustine (BCNU) - 3.3 mg/ml	27.9
Cyclophosphamide - 20.0 mg/ml	>240
Doxorubicin HCl (Adriamycin)2.0 mg/ml	>240
Etoposide (Toposar) - 20.0 mg/ml	>240
Fluorouracil (Adrucil) - 50.0 mg/ml	>240
Methotrexate - 25.0 mg/ml	>240
Paclitaxel (Taxol) - 6.0 mg/ml	>240
Thiotepa (THT) - 10.0 mg/ml	48.6
Vincristine Sulfate - 1.0 mg/ml	>240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 27.9 minutes and Thiotepa: 48.6 minutes. Warning: Do not use with Carmustine.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200671

Device Name
Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Test Chemotherapy drug & Concentration	Average Breakthrough Detection Time (Minutes)
Carmustine (BCNU) - 3.3 mg/ml	23.4
Cyclophosphamide - 20.0 mg/ml	>240
Doxorubicin HCl (Adriamycin) 2.0 mg/ml	>240
Etoposide (Toposar) - 20.0 mg/ml	>240
Fentanyl Citrate Injection - 100 mcg/2mL	>240
Fluorouracil (Adrucil) - 50.0 mg/ml	>240
Methotrexate - 25.0 mg/ml	>240
Paclitaxel (Taxol) - 6.0 mg/ml	>240
Thiotepa (THT) - 10.0 mg/ml	64.9
Vincristine Sulfate - 1.0 mg/ml	>240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 23.4 minutes and Thiotepa: 64.9 minutes. Warning: Do not use with Carmustine.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510K Summary

510(k) Number:

K200671

Submitter:

Ansell Healthcare Products LLC.
2301 Robb Drive
Reno, NV 89523

Contact Person:

Don Cronk
Associate Director, Regulatory Affairs – Americas
Phone: (775) 470-7106
Email: don.cronk@ansell.com

Date Prepared:

6/19/2020

Name of the Device:

Trade Names:	Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Blue Colored Tested for Use with Chemotherapy Drugs Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Green Colored Tested for Use with Chemotherapy Drugs Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Common Name:	Patient Examination Glove
Classification Name:	Patient Examination Glove
Classification Regulation:	21 CFR 880.6250
Device Class:	I
Product Code:	LZA, LZC, QDO
Classification Panel:	Non-powdered patient examination glove

Legally Marketed Predicate Device:

Company:	Ansell Healthcare Products LLC
Trade Name:	Micro-Touch NitraTex Sterile Nitrile Powder-Free Blue Examination Gloves (Chemotherapy Use)
510(k) Number:	K082457
Device Class:	Class I
Product Code:	LZA (Nitrile)
Device Name:	Patient Examination Glove (21 CFR 880.6250)

Device Description:

Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Blue Colored Tested for Use with Chemotherapy Drugs, Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Green Colored Tested for Use with Chemotherapy Drugs, Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate are non-sterile, single use only, disposable, powder free examination gloves. The glove is made of nitrile butadiene rubber. A polyacrylic polymer is applied to the inner surface of the glove to make donning easy.

Characteristic:

- Ambidextrous with beaded cuff and straight fingers
- Finger-textured,
- Blue, green or pink colored
- Containing aloe and chamomile.
- Five (5) sizes – extra-small, small, medium, large, and extra-large.
- Tested against chemotherapy drugs and fentanyl citrate (pink only).

High levels of ozone will degrade rubber material of the glove, therefore the glove should be protected from ozone in particular.

The gloves are designed to meets the specifications of ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application.

Indications for Use Statements:

Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Test Chemotherapy Drug & Concentration	**Average Breakthrough Detection Time (Min)**
Carmustine (BCNU) – 3.3 mg/ml	23.4
Cyclophosphamide – 20.0 mg/ml	>240
Doxorubicin HCl (Adriamycin) – 2.0 mg/ml	>240
Etoposide (Toposar) – 20.0 mg/ml	>240
Fentanyl Citrate Injection – 100 mcg/2mL	>240
Fluorouracil (Adrucil) – 50.0 mg/ml	>240
Methotrexate – 25.0 mg/ml	>240
Paclitaxel (Taxol) – 6.0 mg/ml	>240
Thiotepa (THT) – 10.0 mg/ml	64.9
Vincristine Sulfate – 1.0 mg/ml	>240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 23.4 minutes and Thiotepa: 64.9 minutes. Warning: Do not use with Carmustine.

Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Blue Colored Tested for Use with Chemotherapy Drugs

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Test Chemotherapy Drug & Concentration	Average Breakthrough Detection Time (Min)
Carmustine (BCNU) – 3.3 mg/ml	17.4
Cyclophosphamide – 20.0 mg/ml	>240
Doxorubicin HCl (Adriamycin) – 2.0 mg/ml	>240
Etoposide (Toposar) – 20.0 mg/ml	>240
Fluorouracil (Adrucil) – 50.0 mg/ml	>240
Methotrexate – 25.0 mg/ml	>240
Paclitaxel (Taxol) – 6.0 mg/ml	>240
Thiotepa (THT) – 10.0 mg/ml	67.1
Vincristine Sulfate – 1.0 mg/ml	>240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 17.4 minutes and Thiotepa: 67.1 minutes. Warning: Do not use with Carmustine.

Microflex® Nitrile Patient Examination Glove with Aloe and Chamomile Green Colored Tested for Use with Chemotherapy Drugs

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment for Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Test Chemotherapy Drug & Concentration	Average Breakthrough Detection Time (Min)
Carmustine (BCNU) – 3.3 mg/ml	27.9
Cyclophosphamide – 20.0 mg/ml	>240
Doxorubicin HCl (Adriamycin) – 2.0 mg/ml	>240
Etoposide (Toposar) – 20.0 mg/ml	>240
Fluorouracil (Adrucil) – 50.0 mg/ml	>240
Methotrexate – 25.0 mg/ml	>240
Paclitaxel (Taxol) – 6.0 mg/ml	>240
Thiotepa (THT) – 10.0 mg/ml	48.6
Vincristine Sulfate – 1.0 mg/ml	>240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 27.9 minutes and Thiotepa: 48.6 minutes. Warning: Do not use with Carmustine.

Technological Characteristics:

Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Blue Colored Tested for Use with Chemotherapy Drugs, Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Green Colored Tested for Use with Chemotherapy Drugs, Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate have the following technological characteristics as compared to ASTM or equivalent standards:

Characteristics	**Standard/Test/** **FDA Guidance**	**Result Summary**
Physical Characteristics:		
Dimensions:	ASTM D6319-10	Meets ASTM D6319-10 requirements for length, width and thickness
Length	*Minimum 230mm*	*Minimum 240mm*
Palm width (mm)		
Size – XS	*70 ± 10*	*75 ± 5*
Size – S	*80 ± 10*	*85 ± 5*
Size – M	*95 ± 10*	*95 ± 5*
Size – L	*110± 10*	*105 ± 5*
Size - XL	*120 ± 10*	*115 ± 5*
Thickness (mm) - single-wall		
Finger	*minimum 0.05*	*Finger – min 0.09*
Palm	*minimum 0.05*	*Palm – min 0.06*
Cuff	-	*Cuff – min 0.05*
Physical Properties:	ASTM D6319-10	Meets ASTM D6319-10 requirements for tensile strength and ultimate elongation before and after accelerated aging:
Tensile Strength		
Before Aging	*minimum 14 MPa*	*minimum 16 MPa*
After Aging	*minimum 14 MPa*	*minimum 14 MPa*
Ultimate Elongation		
Before Aging	*minimum 500%*	*minimum 500%*
After Aging	*minimum 400%*	*minimum 400%*
Freedom from holes	ASTM D6319-10 ASTM D5151-06	Meets or exceeds ASTM D6319-10 and ASTM D5151-06 requirements of AQL 2.5

Powder Residual	ASTM D6319-10 ASTM D6124-06	Meets applicable requirement for powder free; ≤ 2 mg per glove
Biocompatibility:		
ISO In Vitro Cytotoxicity	ISO 10993-5:2009	Under the conditions of the study, undiluted, 1:2, 1:4, 1:8, 1:16 dilution was cytotoxic., 1:32 and 1:64 are not cytotoxic
ISO Skin Irritation Study	ISO10993-10:2010	Under the conditions of the study, not an irritant
ISO Maximization Sensitization Study	ISO 10993-10:2010	Under the conditions of the study, not a sensitizer
ISO acute systemic toxicity	ISO 10993-11: 2006	Under the conditions of the study, no evidence of systemic toxicity

Substantial Equivalence:

	Predicate Device	**Proposed Subject Device**	**Substantial Equivalence to Predicate**
Trade name	Micro-Touch NitraTex Sterile Nitrile Powder-Free Blue Examination Gloves (Chemotherapy Use)	Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Blue Colored Tested for Use with Chemotherapy Drugs Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Green Colored Tested for Use with Chemotherapy Drugs Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Not applicable
510k Number	K082457	K200671	Not Applicable
Product Owner	Ansell Healthcare	Ansell Healthcare	Ansell Healthcare
Product Code	LZA	LZA, LZC, QDO	Similar

Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Yes
Regulatory Class	I	I	Yes
Regulation Name	Patient Examination Glove	Patient Examination Glove	Yes
Indications for use	The patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	Yes
Material Composition	Synthetic nitrile rubber	Synthetic nitrile rubber	Yes
Coating	Polyacrylic polymer inner coating to aid donning	Polyacrylic polymer inner coating to aid donning	Yes
Aloe and Chamomile	N/A	Aloe and Chamomile coated on the donning surface	As noted
Design	Non-sterile	Non-sterile	Yes
	Single use	Single use	Yes
	Powder-free	Powder-free	Yes
	Ambidextrous	Ambidextrous	Yes
	Beaded cuff	Beaded cuff	Yes
Color	Blue	Green, Blue, and Pink	As noted
Performance a. **Dimensions**	Meets ASTM D6319-10 requirements	Meets ASTM D6319-10 requirements	Yes
b. **Physical Properties**	Meets ASTM D6319-10 requirements	Meets ASTM D6319-10 requirements	Yes
c. **Freedom from holes**	Meets ASTM D6319-10 requirements of GI, AQL 2.5	Meets ASTM D6319-10 requirements of GI, AQL 2.5	Yes
d. **Powder Residual**	Meets ASTM D6319-10 requirements; Not more than 2.0mg/glove	Meets ASTM D6319-10 requirements; Not more than 2.0mg/glove	Yes

e. **Sterility**	Non-sterile		Non-sterile		Yes
Biocompatibility	Passes Primary Skin Irritation Test and Dermal Sensitization Test		Passes Primary Skin Irritation Test and Dermal Sensitization Test and Acute Systemic Toxicity Test		Yes
Chemotherapy Claim	**Predicate Device**		**Pink Device**		As Noted (Fentanyl Citrate)
	Carmustine (BCNU)	32.1	Carmustine (BCNU)	23.4	
	Cyclophosphamide	>240	Cyclophosphamide	>240	
	Doxorubicin HCl (Adriamycin)	>240	Doxorubicin HCl (Adriamycin)	>240	
	Etoposide (Toposar)	>240	Etoposide (Toposar)	>240	
	Fluorouracil (Adrucil)	>240	Fluorouracil (Adrucil)	>240	
	Methotrexate	>240	Methotrexate	>240	
	Paclitaxel (Taxol)	>240	Paclitaxel (Taxol)	>240	
	Thiotepa (THT)	140.7	Thiotepa (THT)	64.9	
	Vincristine Sulfate	>240	Vincristine Sulfate	>240	
			Fentanyl Citrate Injection	>240	
Chemotherapy Claim	**Predicate Device**		**Blue Device**		Yes
	Carmustine (BCNU)	32.1	Carmustine (BCNU)	17.4	
	Cyclophosphamide	>240	Cyclophosphamide	>240	
	Doxorubicin HCl (Adriamycin)	>240	Doxorubicin HCl (Adriamycin)	>240	
	Etoposide (Toposar)	>240	Etoposide (Toposar)	>240	
	Fluorouracil (Adrucil)	>240	Fluorouracil (Adrucil)	>240	
	Methotrexate	>240	Methotrexate	>240	
	Paclitaxel (Taxol)	>240	Paclitaxel (Taxol)	>240	
	Thiotepa (THT)	140.7	Thiotepa (THT)	67.1	
	Vincristine Sulfate	>240	Vincristine Sulfate	>240	

Chemotherapy Claim	**Predicate Device**		**Green Device**		Yes
	Carmustine (BCNU)	32.1	Carmustine (BCNU)	27.9	
	Cyclophosphamide	>240	Cyclophosphamide	>240	
	Doxorubicin HCl (Adriamycin)	>240	Doxorubicin HCl (Adriamycin)	>240	
	Etoposide (Toposar)	>240	Etoposide (Toposar)	>240	
	Fluorouracil (Adrucil)	>240	Fluorouracil (Adrucil)	>240	
	Methotrexate	>240	Methotrexate	>240	
	Paclitaxel (Taxol)	>240	Paclitaxel (Taxol)	>240	
	Thiotepa (THT)	140.7	Thiotepa (THT)	48.6	
	Vincristine Sulfate	>240	Vincristine Sulfate	>240	

The subject device meets the applicable requirements for patient examination gloves regarding dimensions and sizes, physical properties, freedom from holes, and powder residues as found in the following standards: ASTM D6319, ASTM D5151 and ASTM D6124. The subject device passes biological reactivity testing for dermal sensitization, irritation and acute systemic toxicity, in accord with the ISO 10993 series of standards.

A clinical study was not required for the subject or predicate devices.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject devices are as safe, as effective, and performs as well as the legally marketed device.