



June 13, 2023

Shanghai Suokang Medical Implants Co., Ltd.  
Lixinhua Lixinhua  
Deputy General Manager  
Building 2, No. 613, Suide Rd., Putuo Region, Shanghai,  
200311, P.R. China  
Shanghai, Shanghai 200000  
China

Re: K201153

Trade/Device Name: Tisuthes e-PTFE Surgical Patch  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical Mesh  
Regulatory Class: Class II  
Product Code: OWR, FTL  
Dated: May 22, 2021  
Received: May 27, 2021

Dear Lixinhua Lixinhua:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
David Krause -S

David Krause, Ph.D.  
Deputy Director  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K201153

Device Name

Tisuthes™ e-PTFE Surgical Patch

Indications for Use (Describe)

Tisuthes™ e-PTFE Surgical Patches are indicated for facial plastic and reconstructive surgery.

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.”*

# Shanghai Suokang Medical Implants Co., Ltd.

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## Section 5 - 510(k) Summary

Date of Summary Preparation: 2020.11.19

### 1. Submitter's Identifications

Submitter's Name: Shanghai Suokang Medical Implants Co., Ltd.  
Address: Building 2, No. 613, Suide Rd., Putuo District, Shanghai, China

Contact Person: Lixinhua  
Contact Email: surgithes@vip.sina.com  
Phone number: +86 21 6608 2766 ext.812  
Fax number: +86 66082138

### 2. Correspondent's Identifications

Correspondent's Name: Shanghai Suokang Medical Implants Co., Ltd.  
Address: Building 2, No. 613, Suide Rd., Putuo District, Shanghai, China  
Contact Person: Lixinhua  
Contact Email: surgithes@vip.sina.com  
Phone number: +86 21 6608 2766 ext.812  
Fax number: +86 66082138

### 3. Name of the Device

Device Classification Name: Mesh, Surgical, Polymeric  
Product Code: FTL , OWR

Product Name: Tisuthes™ e-PTFE Surgical Patch  
Trade Name: Tisuthes™ e-PTFE Surgical Patch  
Common Name: Surgical mesh  
Classification Panel: General & Plastic Surgery  
Product Code: FTL , OWR  
Device Classification: Class II

### 4. The Predicate Devices

K021889

Trade/Device Name: Surgiform Augmentation Material

K091011

Trade/Device Name: PureForm ePTFE Facial Implants (Nasal, Chin, Malar)

### 5. Device Description

# Shanghai Suokang Medical Implants Co., Ltd.

5.1 Tisuthes™ e-PTFE Surgical Patches are intended for facial plastic and reconstruction surgery. The device is provided sterile.

The device is available in the forms of sheets, blocks and preformed three-dimensional forms (chin, nasal, temporal piriform and malar) with multiple sizes.

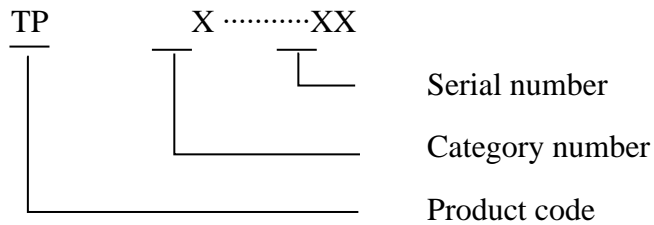
## 5.2. Symbol

TP: Expanded Polytetrafluoroethylene (e-PTFE) Surgical Patch (Brand Name: Tisuthes)

## 5.3 Product numbers definition

### 5.3.1 Marking method

TP:



Category number: S: Soft Patch

R: Block

N: Nasal implants

C: Chin implants

M: Malar implants


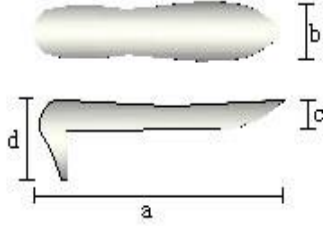
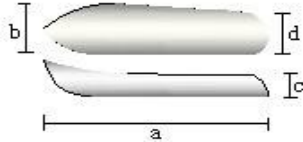
F: Piriform implants

T: Temporal implants

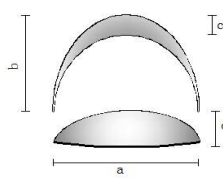
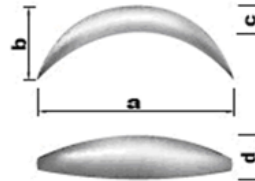
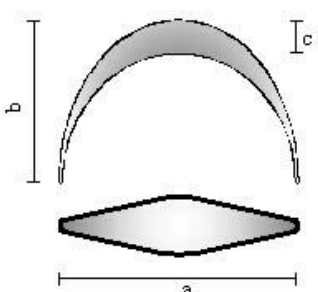
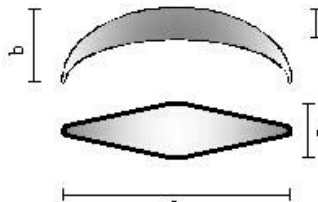
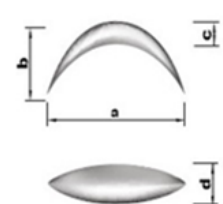
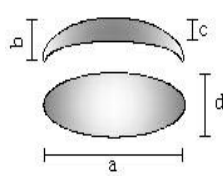
## 5.4 Model and Specification

Soft Patch (TPS)						
Spc.	a (mm)	b (mm)	c (mm)	d (mm)	Tolerance	Diagram
TPS01	60	40	1	/	±10%	
TPS02	60	40	2	/	±10%	
TPS03	60	40	3	/	±10%	
TPS04	60	40	4	/	±10%	
TPS05	80	60	1	/	±10%	
TPS06	80	60	2	/	±10%	
TPS07	80	60	3	/	±10%	
TPS08	80	60	4	/	±10%	

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TPS09	140	60	1	/	±10%	
TPS10	140	60	2	/	±10%	
TPS11	140	60	3	/	±10%	
TPS12	140	60	4	/	±10%	
<b>Block (TPR)</b>						
Spc.	a (mm)	b (mm)	c (mm)	d (mm)	Tolerance	Diagram
TPR01	70	20	5	/	±10%	
TPR02	70	20	8	/	±10%	
TPR03	60	50	3	/	±10%	
TPR04	60	40	5	/	±10%	
TPR05	70	15	8	/	±10%	
TPR06	70	15	6	/	±10%	
TPR07	70	15	5	/	±10%	
TPR08	100	50	5	/	±10%	
TPR09	100	50	8	/	±10%	
<b>Nasal implants (TPN)</b>						
Spc.	a (mm)	b (mm)	c (mm)	d (mm)	Tolerance	Diagram
TPN11	55	16	5.5	20	±10%	
TPN12	65	11	5	20	±10%	
TPN13	55	11	5	20	±10%	
TPN14	55	11	6.5	20	±10%	
TPN15	50	12	5	10	±10%	
TPN16	50	12	6.5	10	±10%	
TPN17	60	12	5	10	±10%	
<b>Chin implants (TPC)</b>						
Spc.	a (mm)	b (mm)	c (mm)	d (mm)	Tolerance	Diagram
TPC01	55	40	8	15	±10%	
TPC02	55	40	12	15	±10%	

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TPC03	55	40	10	15	±10%	
TPC04	60	25	8	15	±10%	
TPC05	60	25	10	15	±10%	
TPC06	55	40	8	15	±10%	
TPC07	62	42	8	15	±10%	
TPC08	62	42	10	15	±10%	
TPC09	60	40	8	15	±10%	
TPC10	50	18	5.5	15	±10%	
TPC11	42	10	5	15	±10%	
TPC12	55	28	8	15	±10%	
TPC13	55	28	10	15	±10%	

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TPC14	55	28	12	15	±10%	
TPC15	60	28	8	15	±10%	
TPC16	60	28	10	15	±10%	
TPC17	60	28	12	15	±10%	
<b>Malar implants(TPM)</b>						
Spc.	a (mm)	b (mm)	c (mm)	d (mm)	Tolerance	Diagram
TPM01	60	28	5	/	±10%	
TPM02	60	28	5	/	±10%	
<b>Piriform Implants (TPF)</b>						
Spc.	a (mm)	b (mm)	c (mm)	d (mm)	Tolerance	Diagram
TPF01	25	22	5	/	±10%	
TPF03	25	22	8	/	±10%	
TPF02	25	22	5	/	±10%	
TPF04	25	22	8	/	±10%	

### 6. Intended Use of Device

Tisuthes™ e-PTFE Surgical Patches are intended for facial plastic and reconstruction surgery.

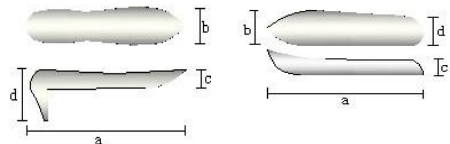
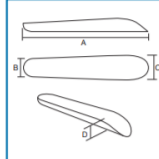
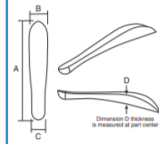
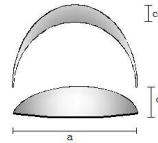
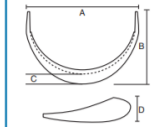
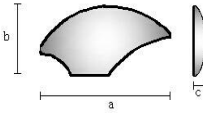
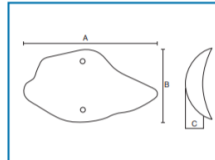
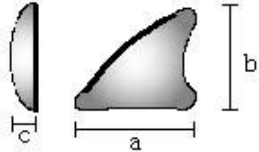
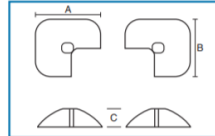


## Shanghai Suokang Medical Implants Co., Ltd.

### 7. Summary of Substantial Equivalence

<b>Product</b>	<b>Proposed device</b> Tisuthes™ ePTFE Surgical Patch K201153	<b>Predicate device</b> Surgiform Augmentation Material K021889	<b>Predicate device</b> Surgiform's PureForm ePTFE Impants K091011	
<b>Indication for use</b>	Tisuthes™ e-PTFE Surgical Patches are intended for facial plastic and reconstructive surgery.	For Plastic and Reconstructive Surgery.	PureForm ePTFE Facial Implants are indicated for use in facial plastic and reconstructive surgery.	
<b>Contraindications</b>	<ul style="list-style-type: none"> <li>Cardiovascular defects</li> <li>Tempormandibular joint (TMJ reconstructions)</li> <li>Cosmetic lip filler</li> <li>Dermal placement</li> </ul>	<ul style="list-style-type: none"> <li>Cardiovascular defects</li> <li>Tempormandibular joint (TMJ reconstructions)</li> <li>Cosmetic lip filler</li> <li>Dermal placement</li> </ul>	<ul style="list-style-type: none"> <li>Tempormandibular joint (TMJ reconstructions)</li> <li>Dermal placement</li> </ul>	
<b>Material</b>	e-PTFE	e-PTFE	e-PTFE	
<b>Design principle</b>	Augmentation or repair of the soft tissue	Augmentation or repair of the soft tissue	Augmentation or repair of the soft tissue	
<b>Physical characteristics</b>	<b>Shapes</b>	The device is available in the forms of sheets, blocks, and preformed three-dimensional forms (chin, nasal, temporal piriform and malar) with multiple sizes.	Flat sheets and Carvable block	
	<b>Dimension (mm)</b>	<u>Sheets:</u> Length: 60, 80,140; Width: 40, 60; Thickness: 1, 2, 3, 4.	<u>Sheets:</u> Length: 80, 190; Width: 30, 70, 170; Thickness: 0.35, 1, 2, 3.	/
		<u>Blocks:</u> Length: 60, 70, 100; Width: 15, 20, 40, 50;	<u>Blocks:</u> Length: 60, 70; Width: 15, 30, 50, 100;	/

# Shanghai Suokang Medical Implants Co., Ltd.

	<p>Thickness: 3, 5, 6, 8.</p> <p><u>Nasal implants[1]: (TPN11~TPN17)</u></p> <p>a: 50, 55, 60; b: 11, 12, 16; c: 5, 5.5, 6.5; d: 10, 20.</p> 	<p>Thickness: 5, 6, 8, 10.</p> <p>/</p>	<p><b>ASIAN STRAIGHT NASAL DORSUM</b></p>  <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Item Code</th> <th>Dim A (mm)</th> <th>Dim B (mm)</th> <th>Dim C (mm)</th> <th>Dim D (mm)</th> </tr> </thead> <tbody> <tr> <td>4AND03</td> <td>50.0</td> <td>7.5</td> <td>9.5</td> <td>4.0</td> </tr> <tr> <td>4AND04</td> <td>50.0</td> <td>8.0</td> <td>10.0</td> <td>4.0</td> </tr> <tr> <td>5AND02</td> <td>50.0</td> <td>7.5</td> <td>9.5</td> <td>5.0</td> </tr> <tr> <td>6AND02</td> <td>50.0</td> <td>8.0</td> <td>10.0</td> <td>6.0</td> </tr> </tbody> </table> <p><b>ASIAN CURVED NASAL DORSUM</b></p>  <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Item Code</th> <th>Dim A (mm)</th> <th>Dim B (mm)</th> <th>Dim C (mm)</th> <th>Dim D (mm)</th> </tr> </thead> <tbody> <tr> <td>4AND01</td> <td>50.0</td> <td>9.5</td> <td>7.5</td> <td>4.0</td> </tr> <tr> <td>4AND02</td> <td>50.0</td> <td>10.0</td> <td>8.0</td> <td>4.0</td> </tr> <tr> <td>5AND01</td> <td>50.0</td> <td>9.5</td> <td>7.5</td> <td>5.0</td> </tr> <tr> <td>6AND01</td> <td>50.0</td> <td>10.0</td> <td>8.0</td> <td>6.0</td> </tr> </tbody> </table>	Item Code	Dim A (mm)	Dim B (mm)	Dim C (mm)	Dim D (mm)	4AND03	50.0	7.5	9.5	4.0	4AND04	50.0	8.0	10.0	4.0	5AND02	50.0	7.5	9.5	5.0	6AND02	50.0	8.0	10.0	6.0	Item Code	Dim A (mm)	Dim B (mm)	Dim C (mm)	Dim D (mm)	4AND01	50.0	9.5	7.5	4.0	4AND02	50.0	10.0	8.0	4.0	5AND01	50.0	9.5	7.5	5.0	6AND01	50.0	10.0	8.0	6.0
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	<p><u>Chin implants:</u></p> <p>a: 42, 55, 60, 62; b: 10, 18, 25, 28, 40, 42; c: 5, 5.5, 8, 10, 12; d: 12.</p> 	/	<p><b>CHIN IMPLANTS</b></p>  <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Item Code</th> <th>Dim A (mm)</th> <th>Dim B (mm)</th> <th>Dim C (mm)</th> <th>Dim D (mm)</th> </tr> </thead> <tbody> <tr> <td>1EC01</td> <td>52.9</td> <td>38.1</td> <td>7.7</td> <td>13.5</td> </tr> <tr> <td>1EC02</td> <td>59.3</td> <td>42.9</td> <td>8.2</td> <td>14.8</td> </tr> <tr> <td>1EC03</td> <td>66.0</td> <td>47.4</td> <td>9.5</td> <td>16.9</td> </tr> </tbody> </table>	Item Code	Dim A (mm)	Dim B (mm)	Dim C (mm)	Dim D (mm)	1EC01	52.9	38.1	7.7	13.5	1EC02	59.3	42.9	8.2	14.8	1EC03	66.0	47.4	9.5	16.9																														
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	<p><u>Malar implants:</u></p> <p>a: 60; b: 28; c: 5.</p> 	/	<p><b>MALAR IMPLANTS (RIGHT AND LEFT)</b></p>  <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Item Code</th> <th>Dim A (mm)</th> <th>Dim B (mm)</th> <th>Dim C (mm)</th> </tr> </thead> <tbody> <tr> <td>1ML01</td> <td>35.0</td> <td>18.0</td> <td>3.5</td> </tr> <tr> <td>1ML02</td> <td>45.4</td> <td>23.0</td> <td>5.0</td> </tr> <tr> <td>1ML03</td> <td>49.4</td> <td>24.0</td> <td>5.7</td> </tr> <tr> <td>1ML04</td> <td>55.0</td> <td>27.1</td> <td>5.8</td> </tr> </tbody> </table>	Item Code	Dim A (mm)	Dim B (mm)	Dim C (mm)	1ML01	35.0	18.0	3.5	1ML02	45.4	23.0	5.0	1ML03	49.4	24.0	5.7	1ML04	55.0	27.1	5.8																														
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	<p><u>Piriform implants</u></p> <p>a: 25; b: 22; c: 5, 8.</p> 	/	<p><b>ASIAN PARA-NASAL</b></p>  <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Item Code</th> <th>Dim A (mm)</th> <th>Dim B (mm)</th> <th>Dim C (mm)</th> </tr> </thead> <tbody> <tr> <td>4PN01</td> <td>20.0</td> <td>18.0</td> <td>4.0</td> </tr> <tr> <td>5PN01</td> <td>20.0</td> <td>18.0</td> <td>5.0</td> </tr> <tr> <td>6PN01</td> <td>21.0</td> <td>19.0</td> <td>6.0</td> </tr> </tbody> </table>	Item Code	Dim A (mm)	Dim B (mm)	Dim C (mm)	4PN01	20.0	18.0	4.0	5PN01	20.0	18.0	5.0	6PN01	21.0	19.0	6.0																																		
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## Shanghai Suokang Medical Implants Co., Ltd.

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<b>Pore Size (microns)</b>	>15	20-40	20-40
<b>Provided sterile</b>	Yes	Yes	Yes
<b>Re-sterilization</b>	Not recommended	May be sterilized up to 3 times	May be sterilized up to 3 times

### **8. Substantial Equivalence:**

Substantial Equivalence discussion:

The proposed devices and the predicated device have the same classification information, same materials, same specifications, same performance effectiveness. The Model of Proposed Device is included in the Model of Predicate device. The Indications for use of proposed device is included in the predicated device. the proposed devices are as safe, as effective and perform as well as the predicate device. Therefore the proposed devices are Substantially Equivalent (SE) to the predicate device which is US legally market device.

**9. Non-Clinical Tests Performed:**

- F754-08 (Reapproved 2015) Standard Specification For Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, And Rod Shapes Fabricated From Granular Molding Powders
- F881-94 (Reapproved 2014) Standard Specification For Silicone Elastomer Facial Implants
- ISO 14630 Fourth Edition 2012-12-01 Non-Active Surgical Implants -- General Requirements
- ISO 10993-1 Fifth Edition 2018-08 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
- ISO 10993-3 Third Edition 2014-10-1 Biological Evaluation Of Medical Devices - Part 3: Tests For Genotoxicity, Carcinogenicity And Reproductive Toxicity
- ISO 10993-4 Third Edition 2017-04 Biological Evaluation Of Medical Devices--Part 4: Selection Of Tests For Interactions With Blood
- ISO10993-5 Third Edition 2009-06-01 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-6 Third Edition 2016-12-01 Biological Evaluation Of Medical Devices -- Part 6: Tests For Local Effects After Implantation
- ISO 10993-7:2008(R)2012 Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-10 Third Edition 2010-08-01 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 10993-11 Third Edition 2017-09 Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity
- ISO 11135:2014 Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices

**10. Conclusion:**

The proposed devices of Tisuthes™ e-PTFE Surgical Patch are determined to be Substantially Equivalent (SE) to the predicate devices.

--- End of this section ---