



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

October 31, 2016

Stradis Healthcare  
% Mr. Carl H. Jenkins  
The Wood Burditt Group  
10 East Scranton Avenue, Suite 201  
Lake Bluff, Illinois 60044

Re: K161483  
Trade/Device Name: Unger Quad Injector  
Regulatory Class: Unclassified  
Product Code: LCJ  
Dated: September 8, 2016  
Received: September 12, 2016

Dear Mr. Jenkins:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

**David Krause -S**

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K161483

Device Name

Unger Quad Injector

Indications for Use (Describe)

The Unger Quad Injector is intended to be used as the needle infusion set component of a tissue expander fill kit for breast tissue expanders designed to be filled with sterile saline using 21-gauge needles. Specifically, the Unger Quad Injector is indicated for assisting the clinician in delivery of sterile saline into the surgically-placed, sub-dermal, temporary, removable tissue expander.

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.

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  
PRASStaff@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."*

### **510(k) Summary**

Date prepared: October 28, 2015

Submitter / Contact Person	H. Carl Jenkins The Wood Burditt Group 10 E. Scranton Ave, Suite 201 Lake Bluff, IL 60044  (ph) 847-234-7500 x 205 (fax) 847-578-0728 (email) hcjenkins@woodburditt.com
Applicant / Specifications Developer / Packager	Stradis Healthcare 805 Marathon Pkwy, Ste 100 Lawrenceville , GA 30046 (ph) 847-596-7716  FDA Establishment Registration Number: 1055754 FEI Number: 1000111025
Manufacturer	Surgistar, Inc 2310 La Mirada Dr. Vista, CA 92081 (ph) 760-598-2480  FDA Establishment Registration Number: 2028661 FEI Number: 3005765014

#### Device

Trade Name	Unger Quad Injector
Proprietary Name	Unger Quad Injector
Common Name	Needle Infusion Set - Breast Tissue Expander Accessory
Classification Name	Breast Tissue Expander - Accessory
Advisory Panel	General and Plastic Surgery Advisory Panel
Regulation	Unclassified
Product Code	LCJ
Classification	Unclassified

### **Reason for 510(k) Submission**

The applicant device is a new device.

### **Device Description**

The Unger Quad Injector is a 'needle infusion set' component to a breast tissue expander fill kit. The device is comprised of four 21 gauge hypodermic lumen needles, which are connected to a needle hub, a luer adapter and tubing.

The Unger Quad Injector was developed with the intent to improve the infusion of saline solution into a tissue expander used in breast augmentation procedures.

### **Indications for Use:**

The Unger Quad Injector is intended to be used as the needle infusion set component of a tissue expander fill kit for breast tissue expanders designed to be filled with sterile saline using 21-gauge needles. Specifically, the Unger Quad Injector is indicated for assisting the clinician in delivery of sterile saline into the surgically-placed, sub-dermal, temporary, removable tissue expander.

### **Predicate and Reference Device Summary Table**

Based on the comparison of the device features, materials, intended use and performance the Unger Quad Injector was shown to be substantially equivalent to the lawfully marketed predicate devices indicated in the table below.

Device	Applicant	510(k) #	Featured Element(s) of Substantial Equivalence
McGhan Tissue Expander Fill System (Predicate Device)	McGhan	K870754	Intended Use / Indications for Use / Technological Characteristics
McGhan Tissue Expander Fill Kit (the needles for which are also marketed as the B.	McGhan	K853014	Intended Use / Indications for Use; Needle Gauge;

Braun Infusion Set – Universal Fill Kit Component  (Reference Device)			Labeling / Technological Characteristics
Terumo Needle  (Reference Device)	Terumo	K121607	Needle Length; Device Color
IMC Hypodermic Needle  (Reference Device)	IMC	K102584	Tip Configuration
K-Pack II Needle  (Reference Device)	K-Pack	K150263	Hub / Needle Bond Strength
Sterilab Needles  (Reference Device)	Sterilab	K961524	Biocompatibility; Materials
Surgistar Blades  (Reference Device)	Surgistar	K923689	Biocompatibility; Materials
Winged Infusion Set  (Reference Device)	Distronic Sterile Products	K955709	Biocompatibility; Materials
Intravascular Administration Set  (Reference Device)	Distronic Sterile Products	K945184	Biocompatibility; Materials
Core-Resistant Huber Infusion Set  (Reference Device)	Distronic Sterile Products	K950597	Biocompatibility; Materials

**Technological characteristics and comparison**

The Unger Quad Injector is substantially equivalent to the McGhan Tissue Expander Fill System (K870754) in terms of technological characteristics and indications for use. The predicate device is comprised, in part, of a 21 G butterfly needle for filling the injection reservoir of the tissue expander.

In addition, several other Reference Devices demonstrate the safety and efficacy of the Unger Quad Injector in terms of supporting scientific methodology and/or standard reference values.

**Summary of the Technological Characteristics of Subject Device and Predicate/Reference Devices (21 CFR 807.92(a)(6))**

Feature	Unger Quad Injector	Predicate and Reference Devices
Design	Needle infusion set component of a tissue expander fill kit for breast tissue expanders; lumen needles at one end of the device; female connector (hub) designed to mate with a male connector (nozzle) of a syringe at the other end of the device.	<p><u>Predicate Device:</u></p> <p>McGhan Tissue Expander Fill System (K870754): “A 21G butterfly needle for filling the injection reservoir of the tissue expander” (p. 7, Attachment 12A).</p> <p><u>Reference Device:</u></p> <p>McGhan Tissue Expander Fill Kit (K853014): Needle infusion set component “for use with Allergan Fill Kit” (lumen needles at one end of the device; hub designed to mate with nozzle of a syringe at the other end of the device).</p>
Gauge	21G	<p><u>Predicate Device:</u></p> <p>McGhan Tissue Expander Fill System (K870754): “A 21G butterfly needle for filling the injection reservoir of the tissue expander”</p>

		<p><u>Reference Device:</u></p> <p>McGhan Tissue Expander Fill Kit (marketed as the B. Braun Infusion Set – Universal Fill Kit Component) (K853014): “21 Ga. Needle Infusion Set”.</p>
Needle Length	38mm	<p><u>Reference Device:</u></p> <p>Terumo Needle (K121607): 21G Needle Length: 38mm</p>
Tip Configuration	Per ISO 7864	<p><u>Reference Device:</u></p> <p>IMC Hypodermic Needle (K102584): Per ISO 7864</p>
Color	Hub color coded following ISO 6009. 21G Needle Color: Green	<p><u>Reference Device:</u></p> <p>Terumo Needle (K121607): 21G Needle Color: Green</p>
Hub / Needle Bond Strength	<p>21G – Minimum 44N</p> <p>Per ISO 7864</p>	<p><u>Reference Device:</u></p> <p>K-Pack II Needle (K150263): 21G – Minimum 44N</p>
Materials	Needle: 304 Stainless Steel Hypodermic Tubing	<p>Same Needle Material (304 Stainless Steel Hypodermic Tubing) used in:</p> <ul style="list-style-type: none"> <li>- K853014 - B. Braun Infusion Set (Predicate Device)</li> <li>- K955709 – Winged and Subcutaneous Infusion Set (Reference Device)</li> <li>- K961524 – Sterilab Sterile Disposable Instruments – Needles - Identical 304 Stainless Steel Hypodermic Tubing. (Reference Device)</li> </ul>

	<p>Needle Cover/Sheath: 640I LDPE (Low Density Polyethylene)</p> <p>ABS Cap and Base: ABS Plastic</p> <p>Tubing: Non-DEHP PVC</p> <p>Luer Lock: White Polypropylene</p> <p>Chevron Pouch – Mylar/Tyvek</p>	<p>Same Cover/Sheath Material used in:</p> <ul style="list-style-type: none"> <li>- K945184 - Intravascular Administration Set (Reference Device)</li> <li>- K950597 – Core-Resistant Huber Infusion Set (Reference Device)</li> </ul> <p>Same ABS plastic used in:</p> <ul style="list-style-type: none"> <li>- K923689 – Surgistar Blades – Handles made of same ABS Plastic (Reference Device)</li> </ul> <p>Same material used for tubing in:</p> <ul style="list-style-type: none"> <li>- K955709 Winged &amp; Subcutaneous Infusion Set (Reference Device)</li> <li>- K945184 – Intravascular Administration Set (Reference Device)</li> </ul> <p>Same material used in luer lock in:</p> <ul style="list-style-type: none"> <li>- K961524 – Sterilab Needles with Polypropylene Hub (Reference Device)</li> </ul> <p>Same Mylar/Tyvek pouches in:</p> <ul style="list-style-type: none"> <li>- K955709 Winged &amp; Subcutaneous Infusion Set (Reference Device)</li> </ul>
--	--	--

Component materials and specifications are presented in the table below:

Description	Material	Dimensions	Additional Specs.
21G Hypodermic Needle	304 Stainless Hypodermic Tubing	2.087" X .0323" OD X .0233" ID	Tri-Facet Grind Bevel
Needle Cover Sheath	640I LDPE	2.5" X .506" OD X .372" ID	Natural Color
ABS Cap and Base	ABS Plastic	1" X .394" OD X .125" ID	ISO 6009 -- 21G Green
Tubing	Non-DEHP PVC	12" X .184" OD X .125" ID	Clear, 70 Durometer
Luer Lock	White Polypropylene	1" X .234" OD Barb X .117" ID	White Plastic
Chevron Pouch	48GA PET/.002 LDPE	7.75" X 3.75"	Clear/White

The Hub/Needle Bond Strength is: Minimum 44N, Per ISO 7864.

**Clinical test:**

No clinical tests were conducted in support of this 510(k) submission.

**Non Clinical Tests performed:**

Bench testing related to performance, safety, effectiveness and specifications of the proposed device was conducted in order to verify the equivalence of performances with the predicate devices.

The following bench testing was conducted on the Unger Quad Injector in support of this 510(k) submission:

Bench Test	Purpose
Pre-clinical Investigational Evaluation of Tissue Expander Inter-operative Filling Device: Stradis Unger Quad Injector	Compare performance of the B. Braun infusion set with the Unger Quad Injector as they perform as part of Tissue Expander Fill Kits
Quad Injector Flow Rate Comparison	Compare performance of the B. Braun infusion set with the Unger Quad Injector as they perform as part of Tissue Expander Fill Kits
Unger Quad Injector Bioburden Test	Bioburden Test
Unger Quad Injector Endotoxin Test	Endotoxin Test
Unger Quad Injector Bioburden Validation Test	Bioburden Validation Test
Shelf Life / Expiration Dating – Aging Testing	Device Functionality and Packaging Integrity
ISO 7864 Hub Needle Bond Strength	To Determine Hub Needle Bond Strength in conformance with ISO 7864
ISO 7864 and ISO 9626	Conformance with ISO 7864 and ISO 9626

The data from the performance testing supports a finding of substantial equivalence because the data demonstrates that the Unger Quad Injector is safely and effectively indicated for use as the 'needle infusion set' component of a tissue expander fill kit for breast tissue expanders designed to be filled with sterile saline using 21 gauge needles. Testing results demonstrate the filling, sealing capability and leakage prevention as compared to lawfully marketed predicate devices. Performance testing results also demonstrate safety and efficacy in terms of biocompatibility, sterilization, shelf life, and general device performance.

**Sterilization:**

Product is EO sterilized. Sterilization validation is in accordance with ANSI/AAMI/ISO 11135-2014, ISO 11135-1 and 11135-2.

The shelf life of the product will be established in accordance with appropriate and valid aging testing results.

**Biocompatibility:**

The Unger Quad Injector components are made with materials identical to equivalent components in other 510(k) cleared devices.

**Conclusion**

The applicant device is substantially equivalent in its intended use, technology / principal of operation, materials, and performance to the predicate devices identified in this 510(k) submission. There is no significant difference that raises any issues of safety or effectiveness.