K131963

# Section 6: 510(k) Summary (21 CFR § 807.92(c))

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| **Submitter:** | TauTona Group, Inc.<br>4040 Campbell Avenue, Suite 110<br>Menlo Park, CA 94025 |
| **Contact:** | Joe Rimsa<br>Chief Operating Officer, TauTona Group<br>Telephone: 650.331.2450<br>Fax: 650.331.2451<br>Email: joerimsa@tautonagroup.com |
| **Date Summary Prepared:** | 22 June 2013 |
| **Device Trade Name:** | TauTona Injector Device |
| **Common Name:** | Piston Syringe (Syringe Assist Device, Syringe Accessory)<br>Syringe Holder, Adaptor |
| **Classification Name:** | Syringe, Piston (21 CFR §880.5860) |
| **Product Code:** | FMF |
| **Equivalent Devices:** | Xpresse Assist / Artiste Device (K083583, cleared 30 June 2009)<br>Tissue Trans Irrigating Syringe (K050797, cleared 13 July 2005) |

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**Device Description:**

The TauTona Injector (TTI) Device is a hand-held, sterile, single-use, disposable device and is designed to be used with, off-the-shelf syringes and injection cannulas. The device is used to assist the physician in injection fluids into the body. The clinician connects the TTI device to the pre-filled syringe and a standard re-injection cannula (Size 9, 14G). The device is activated by a trigger mechanism that enables fluid delivery in specific aliquot sizes. The TTI Device is a simple handle that consists of the following components:

- Pump with an enclosed motor
- Battery pack (12V)
- Controller (printed circuit board with software)
- Dispensing trigger
- On/off/aliquot size select switch
- Indicator light
- Syringe luer connector (female)
- Cannula luer connector (male)

**Intended Use / Indications for Use:**
The TauTona Injector Device is a syringe assist device and is intended for use in the administration of sterile materials / autologous adipose tissue under aseptic conditions in accordance with the best judgment of the clinician. The TauTona Injector Device is intended for use with standard syringes / cannulas.

**Technological Characteristics:**
The TauTona Injector Device is substantially equivalent to the Xpresse Assist / Artiste Device distributed by Nordson Micromedics and the Tissue Trans device distributed by Shippert Medical. Both the subject and predicate devices have similar indications for use, intended uses and operating principles. All three devices are intended to deliver fluids into the body from a prefilled piston syringe. Additionally, both the subject and predicate devices are intended for use with standard off the cannulas for injection of autologous / sterile materials in aesthetic procedures. The Tissue Trans device delivers fluid by applying manual force to a syringe. The TauTona Injector device employs the use of a trigger mechanism to activate a battery powered motor to apply force to a plunger to effect fluid delivery. Similar to the Xpresse Assist / Artiste Device, the TTI Device relies on an energy source to enable fluid delivery. However, the TTI device accomplishes this through a sterile, single-use, hand held battery powered motor as opposed to the Xpress Assist / Artiste Device which relies upon an external source of compressed gas and a power supply to enable fluid delivery. In short, the TauTona Injector is a syringe assist device that is used in the same manner as the predicate devices to assist in injections. The main difference between the predicates and the TauTona Injector Device is the source and control of the force used to drive injections.

**Non-Clinical Performance Data:**
Design verification testing confirmed that the TauTona Injector Device performs according to the stated intended use. Device evaluation consisted of functional testing performed pursuant to TauTona's design verification protocol; comparative testing with the cited predicate devices and human factors testing. Biocompatibility testing was conducted according to ISO 10993 "Biological Evaluation of Medical Devices". The sterilization validation plan complies with the requirements prescribed in ISO 11135 for ethylene oxide sterilization. Electrical safety and electromagnetic compatibility testing was completed pursuant to the requirements outlined in IEC 60601 "Medical Electrical Equipment – General Requirements for Safety". Software validation was conducted pursuant to FDA's Guidance Document titled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005). Packaging and shipping validation studies were conducted pursuant to the applicable ISTA 2A guidelines.

**Summary:**
Based on the product technical information, intended use / indications for use and non-clinical performance data provided in this premarket notification, the TauTona Injector Device has been shown to be substantially equivalent to the currently marketed predicate devices. Test data included in this 510(k) submission demonstrate similar performance of the TauTona Injector device as compared to the

predicate devices. The differences between the subject and predicate devices do not raise new types of safety or effectiveness questions.

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

October 22, 2013

TauTona Group, LLC
C/O Joe Rimsa
Chief Operating Officer
4040 Campbell Avenue, Suite 110
Menlo Park, California 94025

Re: K131963
Trade/Device Name: TauTona Injector Device
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: September 20, 2013
Received: September 23, 2013

Dear Mr. Rimsa:

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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Section 5: Indications for Use Statement

**510(k) Number if Known: TBD**

**Device Name: TauTona Injector Device**

**Indications for Use:**

**The TauTona Injector Device is a syringe assist device and is intended for use in the administration of sterile materials / autologous adipose tissue under aseptic conditions in accordance with the best judgment of the clinician. The TauTona Injector Device is intended for use with standard syringes and cannulas.**

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| **Prescription Use** ☒ **(Part 21 CFR 801 Subpart D)** | **AND/OR** | **Over-The-Counter Use** _____ **(21 CFR 807 Subpart C)** |

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**Concurrent of CDRH, Office of Device Evaluation (ODE)**

Richard C. Chapman
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