510(k) SUMMARY

AESTHETIC SCIENCES CORPORATION
XPRESSE ASSIST DEVICE

Submitter/Sponsor's Name, Address, Telephone Number, Contact Person and Date Prepared:

Aesthetic Sciences Corporation
1455 Adams Drive
Menlo Park, CA 94025
Main Phone: 650-322-9600
Facsimile: 650-322-9601
Contact Person: Denise F. Gottfried

JUN 30 2009

Date Prepared: April 10, 2009

Name of Device: Xpresse™ Assist Device

Common or Usual Name: Piston Syringe (Syringe Assist, Syringe Accessory)
Syringe Holder, Adaptor

Classification Name

Classification:	Class II, Code FMF, 21 CFR 880.5860
Classification Name:	Syringe, Piston (Syringe Assist, Syringe Accessory)

Predicate Device

The XPRESSE Assist Device is substantially equivalent to the Carpuject® Cartridge Syringe Holder Accessory, K820164, and the iSecure Syringe Cartridge Holder, K063180, regarding indication for use, intended use, and operating principle.

The XPRESSE Assist Device does not raise new questions associated with safety and efficacy relative to indication for use, intended use, materials, and technology when compared to the predicate devices or other commercially available medical devices on the US Market. Technological differences between the predicate devices and the XPRESSE Assist Device have been determined to be acceptable in accordance with safety and performance testing results.

Intended Use / Indications for Use

The XPRESSE Assist Device is a syringe assist device intended for use in the administration of sterile materials under aseptic conditions in accordance with the best judgment of the clinician.

Device Description

The XPRESSE Assist Device is a non-sterile, air/gas-powered device that is used to assist the clinician in injecting fluids into the body. The clinician connects the XPRESSE Assist Device to the desired syringe, and uses the foot pedal to activate the XPRESSE Assist Device. When activated, the XPRESSE Assist Device allows flow of compressed air/gas, which pushes the syringe plunger forward, dispensing the syringe contents. The XPRESSE Assist Device is compatible with standard glass or plastic barrel syringes.

The XPRESSE Assist Device includes the following components:

- a controller to provide regulated, compressed air/gas to a syringe (syringe not a part of this device),
- a foot switch connecting to the control unit for clinician activation of the system, and
- a disposable adaptor and tubing unit, with integral plastic tube connecting the controller to the desired syringe.

The controller includes an electrically-powered LED display to indicate system pressure settings and to allow activation/inactivation of the foot pedal. Pressure is adjustable by the clinician from 0 to 100 psi using the controller knob located on the front face plate of the controller. The XPRESSE Assist Device is compatible with either a compressed air canister (45-gram CO_2) or facility compressed air.

Summary of Technological Characteristics Compared to Predicate Devices

The XPRESSE Assist Device as described in this submission is substantially equivalent to the predicate Carpuject® Syringe Holder Accessory and the iSecure Syringe Cartridge Holder with respect to the following characteristics:

- All three devices are indicated for use in assisting the administration of sterile materials
- All three devices are intended to be used with prefilled piston syringes, as an accessory to facilitate injection
- All three devices which come in contact with the piston syringe use the same linear force concept for pushing the piston syringe plunger forward, dispensing the contents of the piston syringe
- All three devices are separate components to that of the prefilled piston syringe

Both predicate devices comprise of a plunger rod with flanges or other surface area for the clinician to grasp. After the holder/accessory device is connected to the piston syringe (cartridge), the clinician applies pressure to the plunger rod which, in turn, applies pressure to the plunger stopper. This action dispels fluid from the piston syringe into the body.

The XPRESSE Assist Device adaptor is used in the same manner as the predicate devices to assist injections. The main difference between the predicates and the XPRESSE Assist Device is the source of force used to drive injection.

The XPRESSE Assist Device uses compressed air/gas as the force needed to apply pressure to the plunger stopper, dispelling fluid from the piston syringe into the body. Using a foot pedal to start or halt the flow of air/gas, the clinician can decide when to begin and stop injection. When the air/gas flow path is open by depressing the foot pedal, regulated compressed air/gas is allowed to flow through the controller to the adaptor, which is connected to the prefilled piston syringe. The foot pedal is released to stop flow.

Note that the prefilled piston syringe is not provided with the XPRESSE Assist Device.

Either a pre-filled gas canister, or clinician-office supplied air/gas, which connects to the XPRESSE Assist Device controller unit may be used as the pressure source. The controller regulates the output pressure to 100psi. Input pressure to the adaptor and syringe plunger is independently regulated from 0 to 100psi by the clinician, who adjusts the pressure to the desired setting as viewed on the controller LED display.

Though the two predicate devices do not include an air/gas-powered feature, such technology is well understood and has been used to power other medical devices cleared via the pre-market notification process by FDA. Such devices are described in the XPRESSE Assist Device 510(k) submission.

Performance Testing

The XPRESS Assist Device has been evaluated for and has passed the criteria for safety and performance testing in accordance with applicable US FDA and internationally-recognized standards for electrical medical devices, including the following:

> IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 (10/31/1995), and
>
> IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)), (07/31/2008).

The XPRESSE Assist Device has also passed verification and validation (V&V) testing criteria in accordance with internal company controls and design control procedures to support the safety and intended use of the product. V&V testing for shelf life, environmental controls and shipping of the product, firmware/software, and product design indicate that the XPRESSE Assist Device performs as intended and in accordance with industry standards and FDA Guidance.

Test data demonstrate substantial equivalency of the XPRESSE Assist Device in performance to the standard, non-assisted approach to injection. Typically, the XPRESSE Assist Device

performed in a more uniform manner and with less overall pressure, allowing greater control than observed using a non-assisted approach.

Substantial Equivalence

The XPRESSE Assist Device is substantially equivalent to the Carpuject® Cartridge Syringe Holder Accessory, K820164, and the iSecure® Syringe Cartridge Holder, K063180. The XPRESSE Assist Device has the same indication for use and intended use as these predicates. The technological differences between the XPRESSE Assist Device and its predicate devices have been evaluated and data demonstrate that the XPRESSE Assist Device is safe for its intended use and performs as intended.

Summary

Based on the information provided in this notification, the subject device warrants the claim for substantial equivalence in accordance with Section 510(k) of the US Federal Food, Drug, and Cosmetic Act ("FDC Act").

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2009

Aesthetic Sciences Corporation
C/O Mr. Jeff D. Rongero
Senior Project Engineer
Underwriter Laboratories, Incorporated
12 Laboratory Drive
Research Triangle Park, North Carolina 27709

Re: K083583
Trade/Device Name: Xpresse Assist Device
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: June 15, 2009
Received: June 17, 2009

Dear Mr. Rongero:

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

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

Enclosure

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Indications for Use Statement

510(k) Number (if known):_____

Device Name: Xpresse™ Assist Device

Indications for Use:

The XPRESSE Assist Device is a syringe assist device intended for use in the administration of sterile materials under aseptic conditions in accordance with the best judgment of the clinician.

Prescription Use ____X (Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use____ (21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K083583