5. 510(K) SUMMARY

510(k) Summary

AUG 2 3 2007

This summary document is being prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

Sean P. Griffin
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Alcon Research, Ltd.
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Date Summary Prepared: August 1, 2007

Device Subject to this 510(k):

Trade Name:	Alcon Small Volume Syringe
Common Name:	Piston Syringe
Classification Name:	Syringe, Piston (per 21 CFR 880.5860)

1. Predicate Devices:

The legally marketed device to which we are claiming substantial equivalence is:

510(k) Number	Device
K941562	BD™ 1mL Polycarbonate Syringe

2. Device Description:

The syringe consists of three main parts: one barrel, one plunger and one stopper. The barrel is made from clear polycarbonate and is designed with printed graduation marks ranging up to 200 µl and a Luer-Lok™ end. The plunger is also made from clear Polycarbonate. The stopper is manufactured using grey or other dark colored non-latex based rubber. The printed graduation marks facilitate appropriate and accurate volume control for the dispensing and containment of fluid by manually application of pressure. The syringe is individually

packaged in a flexible package with a peel-away cover that allows the syringe to remain sterile until opened.

3. Indications for Use:

The Small Volume Syringe is a 200 µl syringe used to inject fluids into, or withdraw fluids from, the body, ports and I.V. lines.

4. Brief Summary of Nonclinical Test and Results:

Safety tests on the Alcon Small Volume Syringe will demonstrate its compliance with applicable requirements of the following standards:

- ISO 7886, Sterile Hypodermic Syringes for Single Use
- ISO 7864, Sterile Hypodermic Needles for Single Use
- ISO 594, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment
- ISO 8537, Sterile, Single-Use Syringes, with or without Needle, for Insulin;
- ANSI/AAMI/ISO 11137:2006, Sterilization of Healthcare Products - Requirements for Validation and Routine Control - Radiation Sterilization

The materials used in the manufacture of the Alcon Small Volume Syringe are the same materials used in the manufacture of other piston syringes currently marketed in the United States.

The Alcon Small Volume Syringe is provided sterile and is intended for single use only. The device will be sterilized by gamma irradiation using validated processes to provide a Sterility Assurance Level (SAL) of 10^{-6}.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Sean P. Griffin
Manager, Regulatory Affairs
Alcon Research, Limited
6201 South Freeway
Fort Worth, Texas 76134

AUG 2 3 2007

Re: K062865
Trade/Device Name: Small Volume Syringe
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: August 9, 2007
Received: August 10, 2007

Dear Mr. Griffin:

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.

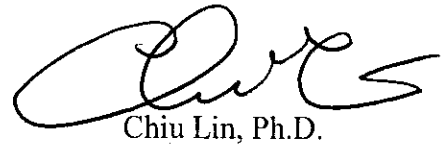
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062865

Device Name: Small Volume Syringe

Indications For Use:

The Small Volume Syringe is a 200 µl syringe used to inject fluids into, or withdraw fluids from, the body, ports and I.V. lines.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ADW

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

510(k) Number: K062865