OCT - 2 2001

## ENTRY-SITE ALIGNMENT SYSTEM (CX9626)

**510(k) SUMMARY**
**(per 21 CFR §807.92)** K012435


**Submitter's Name:** Bausch & Lomb
**Address:** 3365 Tree Court Industrial Blvd.
St. Louis, MO 63122

**Telephone #:** (636) 226-3182
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**Official Correspondent:** Vanada Johnson,
Regulatory Affairs Specialist


**Date Summary Prepared:** September 10, 2001

**DEVICE NAME:** **Entry-Site Alignment System**

Classification Name: Cannula, Trocar, Ophthalmic

Proprietary name: Entry-Site Alignment System (ESA)

Common Name: trocar/cannula

Class: Class I

Panel: Ophthalmic

Product Code: NGY

The marketed device(s) to which substantial equivalence is claimed:

- Alcon/Grieshaber Trocar Cannula Set

**PRODUCT DESCRIPTION:**

Bausch & Lomb's Entry-Site Alignment system (ESA) is a 25ga disposable cannula system used to access the posterior segment of the eye for various ophthalmic surgical procedures. The ESA system is used to establish and maintain a surgical orifice for infusion as well as insertion and removal of surgical instruments used during posterior ophthalmic surgical procedures.

The ESA system will be EtO sterilized with a minimum SAL level of $10^{-6}$. The ESA system will be provided sterile, single-use in the following configuration:

(3) Insertion tool assemblies (needle/cannula)
(3) Cannula plugs
(1) Infusion line

The ESA insertion tool assembly is constructed of polycarbonate handle with a thin wall stainless steel needle affixed to the distal tip of the insertion tool handle, via a medical grade adhesive. The intravenous point of the needle allows for ease of piercing through the conjunctiva and sclera vs. the traditional dissection of the conjunctiva and sclera.

The cannulas are constructed of thin-wall stainless steel with an polycarbonate hub and are manually attached to the ESA insertion tool and locked (via a slight twist) into place (provided pre-assembled). The cannula lumen is designed to accommodate passage of various 25ga surgical instruments for posterior surgical procedures.

The cannula plugs are constructed of a medical grade ABS polymer and are intended for insertion into the entry-site cannula(s) to seal the cannula port when not in use.

The silicone infusion line, connected to a chosen surgical entry site, is intended to infuse through cannula port while performing surgical procedure.

During use, the ESA system is manually advanced through the conjunctiva and sclera. Once an incision is established, the insertion tool/needle is removed and the cannula remains in place at the chosen surgical entry site(s). Following placement of the trocar(s), a chosen cannula port is utilized as an infusion site for which the infusion tube is attached. The desired posterior segment procedure is performed advancing and removing surgical instruments through the lumen of the positioned cannulas. After the procedure is completed the cannulas are simply removed from the eye using forceps.

Currently, vitreoretinal techniques require the dissection of the conjunctiva and the creation of pars plana scleral incisions through which surgical instruments are passed. The instruments are observed through the pupil using a microscope and corrective optics while delicate retinal tissues within the eye are manipulated and dissected. The scleral incision created for vitreoretinal surgery must be large enough to accommodate the required instruments, typically 19 or 20ga in diameter. At the completion of the surgery the scleral incision and conjunctiva are closed and reattached with sutures.

With a strong motivation to move away from procedures that require sutures following surgery, the 25ga ESA system provides another method of insertion and removal of surgical instruments. The 25ga ESA insertion tool needle contains an intravenous point needle/trocar for ease of insertion through both the conjunctiva and the sclera, without the need for the traditional dissection. Piercing the conjunctiva and slcera vs. dissection, could potentially eliminate pars plana as well as the use of sutures as a result of a smaller incision (25ga (.5mm). vs. 19ga and 20ga (1mm)).

**STATEMENT OF INDICATIONS FOR USE**

The ESA is a hand-held surgical instrument intended for use as a trocar/cannula for establishing an entry site conduit for passing ophthalmic instruments/accessories used to perform posterior ophthalmic surgical procedures.

# ENTRY-SITE ALIGNMENT SYSTEM (ESA)

**Indications for Use:**

The ESA is a hand-held surgical instrument intended for use as a trocar/cannula for establishing an entry site conduit for passing ophthalmic instruments/accessories used to perform posterior ophthalmic surgical procedures.

**Contraindications**:
This device is not, in and of itself, a medical treatment device. Therefore, there are no absolute contraindications to its use.

**Cautions and Warnings:**

- Federal (USA) laws restricts this device to sale by or on the order of a physician.
- Single use - DO NOT REUSE.
- Sterility guaranteed unless package opened or damaged.

**Directions for Use:**

1. Carefully remove the protective cap from the Trocar handle without disturbing the ESA cannula.
2. At the desired location, insert the trocar until the cannula hub rests against the conjunctiva.
3. Slide the handle out of the ESA cannula allowing the cannula to remain in place.
4. Insert infusion line or plug into cannula.
5. Introduce appropriate-sized surgical instruments to perform surgical procedure.
6. At the completion of surgical procedure gently remove each cannula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2001

Ms. Vanada Johnson
Regulatory Affairs Specialist
Bausch & Lomb Surgical
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122-6694

Re: K012435
Trade/Device Name: Entry-Site Alignment System (CX9626)
Regulation Number: 21 CFR 886.4350
Regulation Name: Manual Ophthalmic Surgical Instruments
Regulatory Class: Class I
Product Code: NGY - Cannala, Trocar, Ophthalmic
Dated: July 30, 2001
Received: July 31, 2001

Dear Ms. Johnson:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) Number : K012435

Device Name: **Entry-Site Alignment System (ESA)**

Indications for Use:

The ESA is a hand-held surgical instrument intended for use as a trocar/cannula for establishing an entry site conduit for passing ophthalmic instruments/accessories used to perform posterior ophthalmic surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

9-28-01

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012435

(Division Sign-Off)

510(k) Number K012435

Bausch & Lomb Surgical