

JAN - 3 2014

510(k) Summary

The submitter of the 510(k) is:

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Date Summary Modified: January 02, 2014

1. Subject device

Trade name: Bausch + Lomb VIS100 Injector System
Common Name: Intraocular lens Guide
Classification Name: 21 CFR 886.4300

2. Predicate Device:

K113852, Bausch + Lomb IOL Injector

3. Device Description:

The Bausch + Lomb VIS100 Injector System is a sterile, single-use device used to fold and insert an IOL into the human eye. The system provides a tubular pathway through an incision over the iris, allowing delivery of an IOL into the capsular bag.

4. Indications for Use:

The Bausch + Lomb VIS100 Injector System is indicated for folding and injection of Bausch + Lomb intraocular lenses approved for use with this injector.

The indications for use are identical to the indications for use of the predicate device.

5. Brief Summary of Nonclinical Test and Results:

Bench testing was performed on the Bausch + Lomb VIS100 Injector System to determine compliance with ISO 11979-3 (Ophthalmic Implants – Intraocular Lenses – Part 3: Mechanical Properties and Test Methods).

Biocompatibility testing was performed on the Bausch + Lomb VIS100 Injector System and the device was found to be biocompatible as per ISO 10993-5 (Biological Evaluation of medical devices – Part 3: Tests for in vitro cytotoxicity and ISO 10993 -10 (Biological Evaluation of Medical Devices – Part 10 – Tests for Irritation and Skin Sensitization).

6. Clinical Studies

A clinical study was not performed on the Bausch + Lomb VIS100 Injector System.

7. Comparative Analysis

A table comparing the proposed device to the predicate devices is provided below.

Table 1: Comparison of Predicate Device to the Proposed Bausch + Lomb VIS100 Injector System

Characteristic	Predicate K113852 Bausch + Lomb IOL Injector, INJ100	Subject Bausch + Lomb VIS100 Injector System
Indications for use	The Bausch + Lomb IOL Injector is indicated for folding and injection of Bausch + Lomb intraocular lenses approved for use with this injector.	The Bausch + Lomb VIS100 Injector System is indicated for folding and injection of Bausch + Lomb intraocular lenses approved for use with this injector.
Contraindications	None	None
Fundamental Scientific Technology	A single use plunger with a silicone cushion tip is used to push forward and insert the IOL that has been placed in a single use cartridge into the capsular bag. The cartridge has a	A single use plunger with a silicone cushion tip is used to push forward and insert the IOL that has been placed in a single use cartridge into the capsular bag. The cartridge has a hydrophilic coating. As the IOL enters the tip, it is compressed and

	hydrophilic coating. As the IOL enters the tip, it is compressed and folded.	folded.
Materials	<p>Cartridge tip: polyamide with Medicoat A coating</p> <p>Injector body, plunger body: ABS</p> <p>Plunger tip: silicone</p> <p>Cartridge loading chamber: polypropylene</p> <p>Spring: stainless steel</p>	<p>Cartridge: polyamide with Medicoat A coating</p> <p>Plunger body, shooter: ABS</p> <p>Plunger tip: silicone</p> <p>Spring: stainless steel</p>
Single use?	Single use	Single use
Sterile?	Sterile	Sterile
Method of Sterilization	Ethylene oxide	Ethylene oxide
Sterility assurance level	10^{-6}	10^{-6}
Shelf life	12 months	1 month

8. Conclusion

The Bausch + Lomb VIS100 Injector System is substantially equivalent to the predicate device.



January 3, 2014

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

Bausch + Lomb
Ms. Shivani K. Chitalia
Regulatory Affairs Specialist
50 Technology Drive
Irvine, CA 92618

Re: K133146

Trade/Device Name: Bausch + Lomb VIS100 Injector System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I
Product Code: MSS
Dated: December 4, 2013
Received: December 5, 2013

Dear Ms. Chitalia:

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 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>. 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,

Bradley S. Cunningham -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Section 5 – Statement of Indications for Use

510(k) Number (if known):

Device Name: Bausch + Lomb VIS100 Injector System

Indications for Use: The Bausch + Lomb VIS100 Injector System is indicated for folding and injection of Bausch + Lomb intraocular lenses approved for use with this injector.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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