FDA U.S. FOOD & DRUG ADMINISTRATION

APR 16 2019

Microvision, Inc.
Leonard Kastrilevich
President
34 Folly Mill Rd. Suite 200
P.O. Box 1651
Seabrook, New Hampshire 03874-1651

Re: K022186
Trade/Device Name: Scleral Plugs, 19 And 20 Gauge
Regulation Number: 21 CFR 886.4155
Regulation Name: Scleral plug
Regulatory Class: Class II
Product Code: LXP
Dated: July 2, 2002
Received: July 5, 2002

Dear Leonard Kastrilevich:

This letter corrects our substantially equivalent letter of February 26, 2003.

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kesia Alexander

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

Enclosure

510(k) Number (if known): K022186

Device Name: Scleral Plug

Indication For Use:

The scleral plugs are intended to maintain patency of a previously made incision in the sclera of the eye, during ophthalmic surgical procedures.

(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 Ophthalmic Devices
510(k) K022186

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

K022186

FEB 2 6 2003

510(k) Summary
Scleral Plugs
(per 21 CFR 807.92)

1. SUBMITTER NAME AND ADDRESS

MicroVision, Inc.
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P.O. Box 1651
Seabrook, NH 03874-1651

Contact Person: Leonard Kastrilevich, President
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Date Prepared: July 01, 2002
Date Revised: December 20, 2002

2. DEVICE NAME

Trade Name: Scleral Plug
Proprietary Name: Scleral Plugs, 19 and 20 Gauge
Classification Name: Plug, Scleral

3. PREDICATE DEVICE

(K854507) Storz MVS 19 & 20 Gauge Scleral Plug
Storz Instrument Co., St. Louis

4. DEVICE DESCRIPTION

Scleral plugs, 19 and 20 gauge, for use in ophthalmic surgical procedures. Both 19 and 20 gauge plugs are stainless steel. The 19 gauge plugs are gold plated.

5. INTENDED USE

The scleral plugs are intended to maintain patency of a previously made incision in the sclera of the eye, during ophthalmic surgical procedures.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The Micro Vision Scleral Plugs are substantially equivalent to the predicate device by virtue of the following points:

6.1 No change in materials, basic components, or methods of manufacture between this device and the predicate; the raw materials used have been used in the medical industry on similar/identical products since pre-amendment, without any record of patient problems or adverse reactions:

6.2 No change in basic configuration or construction;

6.3 This device has been tested by an independent lab for biocompatibility and will be subjected to inspection and during/after manufacture and prior to release to the field.

6.4 The function and use of this product will be no different then that of the predicate device.

Predicate device is a Class II device, granted FDA marketing clearance under K854507, issued to Storz Instrument Co., St. Louis, Missouri. Substantial equivalency is being claimed to predicate device.

MicroVision, Inc. believes that based on the above comparison, the Micro Vision Scleral Plug is substantially equivalent to the above cited device, that any differences are minor and do not raise new issues of safety and effectiveness.

Signed: Leonard Kastrilevich Dated: 12-23-07

Leonard Kastrilevich
President
MicroVision, Inc.