DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 15, 2017

LV Liberty Vision Corp.
% Paul T. Finger, M.D.
Chief Executive Officer
155 Fleet Street
PORTSMOUTH NH 03801

Re: K163572
Trade/Device Name: LV Liberty Vision Model 1 ^{90}Yttrium Brachytherapy Source
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: December 11, 2016
Received: December 19, 2016

Dear Dr. Finger:

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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163572

Device Name
LV Liberty Vision Model 1 90Yttrium Brachytherapy Source

Indications for Use *(Describe)*

LV Liberty Vision Model 1 90 Yttrium Brachytherapy Source with individual activity up to 20 mCi (740 MBq), is indicated for episcleral brachytherapy of tumors and benign growths. The Model 1 source is intended for use within a manual brachytherapy system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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LV Liberty Vision

Section 5
510(k) Summary

Section 807.92(a)

(1) Submitter

LV Liberty Vision Corp. t: 603.766.0451
155 Fleet Street
Portsmouth, New Hampshire 03801; USA;

Establishment Registration No.: To Be Applied For

Contact Person: Paul T. Finger, MD
Chief Executive Officer
e: pfinger@libertyvision.com

(2) Device Name:

Classification Name: Radionuclide Brachytherapy Source (892.5730) (90 KXK)

Common or Usual Name: Brachytherapy Source

Proprietary Name: LV Liberty Vision Model 1 ^{90}Yttrium Brachytherapy Source

(3) Legally Marketed Predicate Device:

Salutaris Medical Devices, Inc. Smd Sr90-1 Radionuclide Brachytherapy Source, cleared under 510(k) number K142701 dated 24 April 2015

(4) Description of LV Liberty Vision Model 1 ^{90}Yttrium Brachytherapy Source:

LV Liberty Vision Model 1 ^{90}Yttrium Brachytherapy Source is a singly-encapsulated ^{90}Yttrium Brachytherapy Source. It consists of a titanium capsule containing a solid radioactive ^{90}Yttrium element. The radioactive element is hermetically sealed in the titanium capsule and, in use, will be attached to a manual radionuclide applicator system (21 CFR 892.5650).

(5) Intended Use

The intended use of the LV Liberty Vision Model 1 ^{90}Yttrium Brachytherapy Source is for the treatment of tumors and benign growths by temporary episcleral irradiation.

(6) Technological Characteristics:

LV Liberty Vision Model 1 ^{90}Yttrium Brachytherapy Source is similar to the predicate high dose rate brachytherapy source that utilizes beta particles from ^{90}Yttrium.

Technological Characteristic	**LV Liberty Vision Model 1 ^{90}Yttrium Brachytherapy Source**	**Salutaris Medical Devices, Inc. Smd Sr90-1 Radionuclide Brachytherapy Source**
Design	The source consists of a solid ^{90}Yttrium active element, with a maximum diameter of 9.6 mm and a maximum thickness of 0.75 mm, singly encapsulated in metallic titanium with a maximum diameter of 10 mm and a maximum thickness of 1.0 mm.	The source consists of a solid ^{90}Strontium/^{90}Yttrium pellet (0.6 mm dia x ~2 mm long) singly encapsulated in metallic stainless steel (0.8 mm dia x 3.1 mm long) and attached to a capsule leader (0.9 mm diameter x 112 mm long).
Materials Radionuclide Encapsulation	 ^{90}Yttrium Titanium	 ^{90}Strontium/^{90}Yttrium Stainless Steel
Performance Dosimetry: Central Axis Dose Rate at 0.6 mm Dose Rate at 1.0 mm	 6 mm dia source: 1.02 Gy/min-mCi 8 mm dia source: 0.62 Gy/min-mCi 10 mm dia source: 0.42 Gy/min-mCi 6 mm dia source: 0.81 Gy/min-mCi 8 mm dia source: 0.50 Gy/min-mCi 10 mm dia source: 0.34 Gy/min-mCi	 0.81 Gy/min-mCi 0.52 Gy/min-mCi
Sterility	This source never directly contacts the patient; sterility is not required.	This source assembly never directly contacts the patient; sterility is not required.
Biocompatibility	This source never directly contacts the patient; biocompatibility assessment is not applicable. The outside of the entire assembly is fabricated from titanium, which is a biocompatible material.	This source assembly never directly contacts the patient; biocompatibility assessment is not applicable. The outside of the entire assembly is fabricated from stainless steel, which is a biocompatible material.
Mechanical Safety	ISO 2919/ANSI N43.6 Class C53211 Applied for New Hampshire Registration	ISO 2919/ANSI N43.6 Class C53X11 Massachusetts Sealed Source Registration LA-1390-S-101-S
Chemical Safety	This source assembly never directly contacts the patient; chemical safety assessment is not applicable. The outside of the entire assembly is fabricated from titanium, which will not chemically react with body tissue.	This source assembly never directly contacts the patient; chemical safety assessment is not applicable. The outside of the entire assembly is fabricated from stainless steel, which will not chemically react with body tissue.
Energy Delivered	^{90}Yttrium (half-life: 2.67 days) decays by beta emission. The ^{90}Yttrium beta has an end-point energy of 2280 keV and an average energy of 934 keV.	^{90}Strontium/^{90}Yttrium (half-life: 28.79 years) decays by beta emission. The ^{90}Yttrium is in secular equilibrium with the ^{90}Strontium. The ^{90}Yttrium beta has an end-point energy of 2280 keV and an average energy of 934 keV. The ^{90}Strontium beta has an end-point energy of 546 keV and an average energy of 196 keV. The range of 196 keV betas is less than 0.5 mm of tissue, and therefore has no therapeutic effect. The therapeutic effect is virtually exclusively from the ^{90}Yttrium betas.

Compatibility with Environment and Other Devices	^{90}Yttrium is a radioactive material and should be strictly controlled. The source should only be used following the conditions and limitations specified by the licensing authority (NRC or Agreement State). The source should be stored in a shielded container with which it is used or the transport container in which it is delivered. If any source cannot be accounted for, the loss should be reported to the federal or state licensing agency. Store at normal room temperature. When disposal is indicated, sources should be disposed of in accordance with the requirements of the institution's radioactive material license. In general, these sources can be disposed of by means of a "Decay in Storage" method approved by the regulatory authority in accordance with 10 CFR 35.92 or equivalent state regulations. Because of the short halflife, sources which have been stored for 60 days may be checked for radioactive content and, if less than 5 nCi, be disposed of in normal waste. Alternatively, radioactive material should be transferred to an authorized recipient, typically the source supplier.	^{90}Strontium/^{90}Yttrium is a radioactive material and should be strictly controlled. The source should only be used following the conditions and limitations specified by the licensing authority (NRC or Agreement State). The source should be stored in a shielded container with which it is used or the transport container in which it is delivered. If any source cannot be accounted for, the loss should be reported to the federal or state licensing agency. Store at normal room temperature. When disposal is indicated, radioactive material should be transferred to an authorized recipient, typically the source supplier. Radioactive material should never be disposed of in normal waste.
Where Used	This source should only be used within a properly designed room following the conditions and limitations specified by the licensing authority (NRC or Agreement State).	This source should only be used within a properly designed room following the conditions and limitations specified by the licensing authority (NRC or Agreement State).
Standards Met Mechanical	ISO 2919/ANSI N43.6	ISO 2919/ANSI N43.6
Electrical Safety	Not Applicable	Not Applicable
Thermal Safety	Not Applicable	Not Applicable
Radiation Safety	This ^{90}Yttrium source is radioactive, and appropriate precautions must be taken during handling to minimize radiation exposure to personnel. Personnel monitoring is required. This source should only be used within a properly designed room following the conditions and limitations specified by the licensing authority (NRC or Agreement State). In circumstances where emergency	This ^{90}Strontium/^{90}Yttrium source is radioactive, and appropriate precautions must be taken during handling to minimize radiation exposure to personnel. Personnel monitoring is required. This source should only be used within a properly designed room following the conditions and limitations specified by the licensing authority (NRC or Agreement State). In circumstances where emergency

	operations must be performed, the operator should use proper applicators, maintain safe working distances and work as rapidly as safely possible to minimize radiation exposure.	operations must be performed, the operator should use proper applicators, maintain safe working distances and work as rapidly as safely possible to minimize radiation exposure.

Section 807.92(b)

(7) Nonclinical Tests

Physical Testing

The LV Liberty Vision Model 1 ^{90}Yttrium Brachytherapy Source has been subjected to the tests specified in American National Standard (ANSI) N43.6 and International Organization for Standardization (ISO) Standard 2919, as referenced in the FDA "Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources" dated 2 August 2000.

Prototype sources were subjected to the tests specified in ANSI N43.6-2007 and ISO 2919-2012 and have equaled or exceeded the requirements corresponding to a classification of C53211, which is the requirement for brachytherapy sources. This exceeds to the physical testing of the predicate device.

Dosimetry

The dose distribution around the LV Liberty Vision Model 1 ^{90}Yttrium Brachytherapy Source was calculated by Monte Carlo simulation. This is equivalent to the dosimetry of the predicate device.

(8) Clinical Tests

Not Applicable

(9) Conclusions

The results of the nonclinical physical testing and the dosimetric analysis, demonstrate that the LV Liberty Vision Model 1 ^{90}Yttrium Brachytherapy Source is as safe, as effective, and performs as well or better than the legally marketed predicate device, Salutaris Medical Devices, Inc. Smd Sr90-1 Radionuclide Brachytherapy Source, cleared under 510(k) number K142701 dated 24 April 2015.