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

August 20, 2015

Medeon Biodesign, Inc.
% Greta Chang
Sr. Manager of Regulatory, Quality and Clinical Affairs
Lin & Associate, LLC
9223 Cambridge Manor Court
Potomac, MD 20854

Re: K151117
Trade/Device Name: Laparoscope Lens Shield Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: July 13, 2015
Received: July 15, 2015

Dear Greta Chang,

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K151117

Device Name
Laparoscope Lens Shield Device (LENS)

Indications for Use *(Describe)*
Laparoscope Lens Shield Device (LENS), a sterile, single-use and disposable laparoscopic accessory lens shield device, is intended to maintain the intra-operative view of the surgical site during minimally invasive surgery by physically shielding the laparoscope lens from debris, grease, blood, and bodily fluids.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 510(k) Summary

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92

.

The assigned 510(k) Number: TBD

1. **Submitter**

Mailing Address	**Medeon Biodesign, Inc** 7F, 116, HouGang St, Taipei, Taiwan 11170 Phone: +886 2 2881 6686 Establishment Registration No.: NA (1st submission)
Contact Person	**Greta Chang** Sr. Manager of Regulatory, Quality & Clinical Affair
Phone:	+886 2 2881 6686
Fax:	+886 2 2881 6685
E-mail:	greta@medeonbio.com
Date Prepared	April 24, 2015

2 **Device Name**

Common or usual name	Laparoscope Lens Shield Device (LENS)
Product Code	GCJ
Device	Endoscope and accessories
CFR Classification	CFR Part 876.1500
Device Class	II
Classification Panel	Gastroenterology/Urology

3 **Predicate Device Name**

510(k) number:	K080613
Trade or proprietary or model name:	Clear-Vu System
Manufacturer:	Minimally Invasive Devices, LLC

4 **Device Description:** The Laparoscope Lens Shield Device (LENS) is a laparoscope accessory lens shielding device consisted of multi-lumen sheath that slides over the laparoscope. The sheaths assembly consists of 3 concentric sheaths: one outer and two inner sheaths. The outer sheath provides protection and cover for the inner sheath and shielding film. It is intended to maintain the intra-operative view of

		the surgical site during minimally invasive surgery by physically shielding the laparoscope lens from debris, grease, blood, and bodily fluids The Laparoscope Lens Shield Device (LENS) is intended to be used by clinicians through prescription use only.
5.	**Intended Use:**	Laparoscope Lens Shield Device (LENS), a sterile, single-use and disposable laparoscopic accessory lens shield device, is intended to maintain the intra-operative view of the surgical site during minimally invasive surgery by physically shielding the laparoscope lens from debris, grease, blood, and bodily fluids.
	Special Conditions for Use Statement(s):	For prescription use only
6.	Technological Characteristics and Substantial Equivalence Comparison with Predicate:	A comparison of the device features, intended use, and other information demonstrates that the Laparoscope Lens Shield Device (LENS) is substantially equivalent to the predicate device as summarized in ***Table 1***. The differences raise no different question of safety and effectiveness.

Table 1

Similarities		
Device name	**Subject device: Laparoscope Lens Shield Device (LENS)**	**Predicate device: Clear-Vu**
Intended Use	Laparoscope Lens Shield Device (LENS), a sterile, single-use and disposable laparoscopic accessory lens shield device, is intended to maintain the intra-operative view of the surgical site during minimally invasive surgery by physically shielding the laparoscope lens from debris, grease, blood, and bodily fluids	Clear-Vu System is a single-use, disposable laparoscopic accessory device intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.
Target patient Population	Patient under laparoscopic surgery	Same
Target User Population	Clinician who is qualified to perform a laparoscopic surgery.	Same
Anatomical Site	Abdominopelvic cavity	Same
Where Used	Hospital O.R. room	Same

Similarities		
Device name	**Subject device: Laparoscope Lens Shield Device (LENS)**	**Predicate device: Clear-Vu**
Contraindications	There's no known contraindications for subject device	Same
Method of Introduction	Subject device is introduced into abdominopelvic cavity via a trocar.	Same
Compatibility Other Devices	Laparoscope :0°, 10mm, 30cm scope Trocar: 12mm	Same
Performance	Able to maintain laparoscopic view when it get soiled by debris	Same
Biocompatible for Intended Use	Limited exposure, external communication device of tissue contact Pass the cytotoxicity, sensitization, irritation, and acute systemic toxicity	Same
Differences		
Device name	**Subject device: Laparoscope Lens Shield Device (LENS)**	**Predicate device: Clear-Vu**
Sterilization Method	Ethylene Oxide sterilization, SAL of 10^{-6}	Radiation sterilization, SAL of 10^{-6}
Energy source	No energy source	CO_2 Gas
Physical barrier	PET film	CO_2 Gas

7. Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specification for its intended use. The following tests were performed on the device.

Biocompatibility testing

The biocompatibility evaluation and testing of the Laparoscope Lens Shield Device (LENS) was conducted in accordance with the following standards and guidance, as recognized by the FDA:

- FDA Draft Guidance - Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing", dated 04-23-2013
- ISO 10993-5, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- 10993-10, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization
- ISO 10993-11, Biological evaluation of medical devices- Part 11: Tests for systemic toxicity.

Sterilization validation

Sterilization validation was conducted in accordance with ISO 11135:2014 “Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices”. Sterilization has been validated to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

Mechanical testing

Laparoscope Lens Shield Device (LENS)'s mechanical function and structure integrity were tested and demonstrated that the design specification from design input are fulfilled. Mechanical safety tests were also conducted to demonstrate that the insertion portion of the device remains intact during the surgery and raises no safety concern.

Image quality test

Laparoscope Lens Shield Device (LENS) had been tested for view quality during laparoscopic procedures regarding the resolution, distortion, field of view, depth of view, and color, to demonstrate that adequate view quality of laparoscopy is maintained to a safe and effective clinical use.

8. Conclusion. Based on the intended use and/or indications for use, technological characteristics, performance testing and comparison to the predicate device, the Laparoscope Lens Shield Device (LENS) is substantially equivalent to the predicate device and raises no different question of safety or effectiveness.