DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 21, 2016

Medeon Biodesign, Inc.
Greta Chang
Sr. Manager of Regulatory, Quality & Clinical Affair
7F, 116, HouGang St,
Taipei, 11170
Taiwan

Re: K160172
Trade/Device Name: Laparoscope Lens Shield Device (LENS)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 23, 2016
Received: March 24, 2016

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,

Herbert P. Lerner -S

for 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

Section 5. Indications for Use Statement

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 on last page

510(k) Number (if known)
~~Pending~~ K160172

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.

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FORM FDA 3881 (9/13) **page 1/1** **PSC Publishing Services (301) 443-6740**

Section 6. 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
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	E-mail:	greta@medeonbio.com
	Date Prepared	January 25, 2016
2	**Device Name**	
	Common or usual name	Laparoscope Lens Shield Device
	Product Code	GCJ
	Device	Endoscope and accessories
	CFR Classification	CFR Part 876.1500
	Device Class	II
	Classification Panel	Gastroenterology/Urology
3	**Predicate k number**	K151117
4	**Device Description:**	The Laparoscope Lens Shield Device (LENS) is a laparoscope accessory lens shielding device consisting of multi-lumen sheath that slides over the laparoscope. The sheath assembling consists of 2 concentric sheaths: one outer and one end-to-end connected 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.

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. Intended use of the modified device, as described in its labeling, has not changed as a result of the modification. This is the same intended use as previously cleared for the LENS K151117.
	Special Conditions for Use Statement(s):	For prescription use only
6.	**Technological Characteristics and Substantial Equivalence Comparison with Predicate**:	Modifications to design and material of the previously 510(k) cleared Laparoscope Lens Shield Device (K151117) resulted in 3 different models to accommodate various laparoscopes. A comparison of the device features, intended use, and other information demonstrates that the modified device is substantially equivalent to the predicate device as summarized in **Table 1**. The differences raise no different questions of safety or effectiveness.

Table 1: Substantially Equivalent Table

Similarities		
Device name	**Predicate device: 10 mm/0° (L030) (K151117)**	**Modified device: 10 mm/0°(L030), 10 mm/30°(L330), and 5 mm/0°(S030)**
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	Same
Target patient Population	Patient under laparoscopic surgery	Same

Similarities		
Device name	**Predicate device: 10 mm/0° (L030) (K151117)**	**Modified device: 10 mm/0°(L030), 10 mm/30°(L330), and 5 mm/0°(S030)**
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
Contraindications	There are no known contraindications for modified device	Same
Method of Introduction	Predicate device is introduced into abdominopelvic cavity via a trocar.	Same
Performance	Able to maintain laparoscopic view when it gets soiled by debris	Same
Biocompatible for Intended Use	Limited exposure, external communication device of tissue contact. All patient contacting parts form final device pass the cytotoxicity, sensitization, irritation, and acute systemic toxicity.	Same
Sterilization Method	Ethylene Oxide sterilization, SAL of 10^{-6}	Same
Energy source	No energy source	Same
Compatibility	**Laparoscope:** 10 mm/ 0°, 30cm scope **Trocar:** 12mm	**Laparoscope**: 10 mm/0° /30 cm, 10 mm/30°/30cm, and 5 mm/0°/30cm **Trocar:** 12 mm and 7 mm

7. Performance Testing

The following performance testing for the design modification demonstrated substantial equivalence to the previously cleared predicate:

Biocompatibility testing

Per material change, 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.

Mechanical testing

The modified device's mechanical function and structure integrity were tested and demonstrated that the design specification from design input are fulfilled and the design modifications do not alter the device safety and function.

Functional testing

Device functionality was tested in the animal model to demonstrate that the intended use is fulfilled. Design modifications do not alter the device function and intended use.

8. Conclusion. Based on the intended use, technological characteristics, performance testing and comparison to the predicate device, the modified device is substantially equivalent to the predicate device and raises no different question of safety or effectiveness.