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

June 2, 2017

Mynosys Cellular Devices, Inc.
Dan Marinsik
VP, Quality, Clinical & Regulatory Affairs
46710 Fremont Blvd.
Fremont, CA 94538-6538

Re: K170655
Trade/Device Name: Zepto
Regulation Number: 21 CFR 886.4100
Regulation Name: Radiofrequency Electrosurgical Cautery Apparatus
Regulatory Class: Class II
Product Code: PUL
Dated: April 25, 2017
Received: April 28, 2017

Dear Dan Marinsik:

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,

Denise L. Hampton -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

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)*
K170655

Device Name
Zepto™

Indications for Use *(Describe)*
Zepto™ is indicated for use in performing anterior capsulotomy during cataract surgery.

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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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Mynosys Cellular Devices, Inc. 46710 Fremont Blvd. Fremont, CA. 94538
Contact	Dan Marinsik
Phone Number	510-857-6296
FAX Number	510-689-2349

Date Prepared	5-26-17
TRADE NAME:	**ZEPTO™**
COMMON NAME:	Capsulotomy Device
DEVICE	Device Class - II
CLASSIFICATION:	
NAME:	Radiofrequency electrosurgical cautery apparatus
PRODUCT CODE	NCR
REGULATION NUMBER:	21 CFR § 886.4100
PREDICATE DEVICE	The Fugo Blade (K001498)

SUBSTANTIALLY EQUIVALENT TO:

The Fugo Blade	(K001498)	

Description of the Device Subject to Premarket Notification:

The Zepto™ is an electrosurgical device indicated for use in performing anterior capsulotomies during cataract surgery. The Zepto™ Capsulotomy System consists of a console, disposable handpiece, and a fluid isolator assembly (consisting of the fluid isolator, roller dispenser, and clamp). The handpiece power cord connector is connected to the front panel of the console to provide power for the capsulotomy procedure. The medical grade PVC suction tubing from the handpiece is connected to the fluid isolator. The fluid isolator is then connected to the console's front panel to provide suction during the treatment to a silicone suction cup containing the capsulotomy element. The Zepto™ console delivers pulsed DC energy from a storage capacitor to a circular capsulotomy element on the tip of the disposable handpiece for creation of a nominal 5mm diameter capsulotomy.

Statement of Intended Use

The intended use for Zepto™ is as a surgical instrument to be used by ophthalmic surgeons for performing anterior capsulotomy during cataract surgery. The device includes durable hardware for multi-use, a disposable handpiece and fluid isolator assembly for single-patient use . The Zepto™ is a prescription (Rx) device to be used by, or on the order of a licensed physician.

Indication for Use

Zepto™ is indicated for use in performing anterior capsulotomy during cataract surgery.

Technological Characteristics Comparison

The Zepto™ shares many technological characteristics including indications and technological features to those of the predicate device, The Fugo Blade. The Zepto™ also utilizes the same mechanism of action to perform the capsulotomy and is therefore substantially equivalent to the legally marketed predicate device. Differences between the Zepto and the predicate device are well-defined and well-characterized and do not raise any new concerns of safety. Key characteristics are provided in the table below.

Attributes	Zepto™ (K170655)	The Fugo Blade (K001498)	Comment
INTENDED USE			
Manufacturer	Mynosys Cellular Devices	Medisurg Ltd.	
Clearance Date	-	08/10/2000	
Model Number	12684, 12430, 12686	M100	
FDA Regulation	21 CFR 886.4100	21 CFR 886.4100	Same
Regulation Name	*Radiofrequency electrosurgical cautery apparatus*	*Radiofrequency electrosurgical cautery apparatus*	Same
FDA Classification Product Code	NCR	NCR	Same
FDA Medical Device Classification	Class - II	Class - II	Same
Single Use Disposable Component(s)	Zepto™ Handpiece and fluid isolator assembly are single use disposables	The Fugo Blade tip is a single use disposable	Same
Prescription (Rx)/Over-the-Counter (OTC)	Rx	Rx	Same
TECHNOLOGICAL CHARACTERISTICS			
Energy Type	Rectified RF Pulsed-DC	RF	Fugo Blade uses full wave RF, Zepto™ uses rectified RF
Induction of capsule tensile stress	Yes, by suction pressure	Yes, by manipulation of probe tip against capsule tissue to be cut	SE, induced by different mechanical means
Electrical	110 VAC 50-60 Hz	4 size "C" rechargable batteries provide DC current for the Fugo Blade Battery Charger: 100-240 VAC, 50/60 Hz, 1.0A	Same, both electrically powered
Electrical Classification	Type BF	Type BF	Same

Attributes	Zepto™ (K170655)	The Fugo Blade (K001498)	Comment
Control	Firmware and button control	Firmware, footswitch and variable power and intensity control	Both are microprocessor controlled. Fugo Blade has power and intensity controls on the console based on the individual Physician's speed in performing Capsulotomy. Zepto™ has a factory preset power output that is slightly lower due to the cutting element being circular in design.
System Components	Handpiece, control console, fluid isolator assembly (see **Fig. 12.1**)	Handpiece, control console footswitch (see **Fig. 12.1**)	Equivalent
Dimensions (Control Box)	13.5" X 10" X 6.5"	10.00" X 7.05" X 6.12"	Both consoles are portable
Emergency Off	Yes	Yes	Same
Foot Switch Controlled	No	Yes	The Fugo Blade utilizes a footswitch to provide power to the treatment tip. The power of the Zepto is delivered via the Cut/Release button
Procedure Halt Using Foot Switch	No	Yes	The Fugo Blade utilizes a footswitch, Zepto utilizes an emergency Stop Button on console
On Switch	Yes	Yes	Same
Display Panel	Yes	Yes	Same
Mains Switch	Yes	Yes	Same
Disposable Cutting Element	Yes	Yes	Same

Attributes	Zepto™ (K170655)	The Fugo Blade (K001498)	Comment
Cutting Element Shape	Circular	Straight	SE - Fugo Blade straight cutting element requires 7-15 seconds to perform capsulotomy, Zepto™ circular cutting element completes capsulotomy in 4 msec
Capsulotomy Size	5.0 mm (nominal)	Variable Dependent on Surgeon	SE - Fugo Blade capsulotomy varies in diameter due to manual circular manipulation of the straight cutting tip. Zepto™ has uniform capsulotomy diameter based on a circular cutting element
MANUFACTURING			
Biocompatibility	The Zepto™ Handpiece passed testing performed according to ISO 10993-5 (Cytotoxicity), 10993-10 (Acute Systemic Toxicity) and 10993-11(Sensitization and Irritation).	There is no mention in the company's literature, website or 510(k) summary as to whether the Fugo Blade was tested for biocompatibility.	The Zepto™ is made from Biocompatible materials, The Fugo Blade is presumed to be the same.
Sterilization	EtO	Heat Autoclave or EtO	Same - Both use validated sterile methods presumed to provide SAL of 1×10^{-6}
Packaging	Zepto™ Handpiece: sterile single pouched Tyvek® bag	Fugo Blade tip: single pouched Tyvek® bag in box of 12 tips	Same
Shelf Life	12 months	Unknown	The Zepto™ has a validated shelf life. The Fugo Blade I presumed to be the same.

Brief Summary of Nonclinical Tests and Results

Mynosys has developed the Zepto™ for use in anterior capsulotomy. Nonclinical testing included pre-clinical animal studies and bench testing.

Summary of Pre-Clinical Testing

A GLP study was conducted that demonstrated the effectiveness of the device in 20 out of 20 rabbit eyes. This study also verified that there was negligible temperature change in the anterior chamber during Zepto™ use. In addition, there were no differences in the endothelial cell condition and ocular histopathology of eyes or the overall condition of eyes that received a Zepto™ capsulotomy compared to fellow eyes that received a CCC. The study also confirmed that there was no observable zonular stress during a Zepto™ capsulotomy.

Summary of Bench Testing

A paired human cadaver eyes study compared the strength and extensibility of the Zepto™ capsulotomy edge with that of femtosecond laser and CCC. (The predicate device was not available for this study.) This study demonstrated overall general safety of the Zepto™. The biomechanical testing of capsulotomy edge properties resulting from different methods of capsulotomy in paired human cadaver eyes provides direct quantitative assessment of edge strength and extensibility. Pairwise comparison of Zepto™ capsulotomies in one eye and either CCC or femtosecond laser capsulotomy in the fellow eye of the same donor provide the most scientifically rigorous evaluation of their relative performance and rule out confounding donor related factors.

The results of the Capsule Edge Strength Study (COCESS) using paired cadaver eyes show that the extensibility of the Zepto™ capsule edges as quantified by stretch ratios were significantly greater than that of capsule edges produced by CCC or by femtosecond laser. The data show that Zepto™ capsulotomies should also exhibit greater extensibility when compared to the predicate device.

Microcalorimetry Validation Test Report

Microcalorimetry testing demonstrated that the Zepto™ is equivalent to the predicate device in energy used during performance of capsulotomies in cataract surgery.

Brief Summary of Clinical Tests and Results

A clinical trial of the Zepto™ was conducted to evaluate its performance in the creation of anterior capsulotomies during cataract surgery. This clinical study was undertaken to address specific questions of safety and effectiveness related to demonstrating substantial

equivalence.

Primary Safety Endpoint: Safety of the ZeptoTM was evaluated by comparing the observed event rate against the historically derived rate for the "gold standard" surgical technique of continuous curvilinear capsulorrhexis (CCC). No posterior capsule rupture and vitreous loss in 100 eyes treated with Zepto.

Primary Effectiveness Endpoint: Capsulotomy effectiveness was determined by evaluating the completeness of the Zepto capsulotomy. The effectiveness analysis revealed 2 cases of incomplete capsulotomy out of 100 cases performed. Successful Zepto 360 degree capsulotomy in 98 of 100 subjects treated with Zepto. Two eyes required manual capsulotomy, both with good visual outcome and IOL capsular fixation, and without adverse outcomes:

- 1 case was attributed to user error (simultaneous energy applied and suction release);

- 1 case with small tissue bridge observed after Zepto procedure was completed manually, attributed to suboptimal surgical microscope visualization, leading to application of Zepto energy before complete apposition of Zepto capsulotomy ring with the capsule was observed.

Additional Safety Parameters:

- **AC Tear:** 2 of 100 eyes treated with Zepto had anterior capsule tear, neither with vitreous loss:
  - 1 case noted at end of surgery with secondary PC tear extending during exchange of damaged IOL;
  - 1 case attributed to cataract chopping technique, did not extend to posterior capsule.
- **Corneal Touch:** No cases reported.
- **Adverse Events:** epithelial erosion and macular edema, anterior capsule tear, anterior and posterior capsule tear without vitreous loss, IOP elevation, and ache in treated eye. Only 1 case (ac/pc tear) was noted to be device-related.

Additional Effectiveness Parameters:

- **Diameter and Circularity of Capsulotomy:** Mean anterior capsule diameter 5.14 mm +/- S.D. 0.14 mm (range 4.9-5.5 mm). 99 cases recorded as circular without zonular damage.
- **Pre- and Post Zepto Corneal Incision Size:** Mean increase in incision size post-Zepto treatment 0.0305 mm (range 0-0.2 mm).
- **Ease of cortex removal:** 97/100 cases reported as similar or easier ease of cortex aspiration as compared to manual capsulorhexis.
- **Capsulotomy centration:** 96/100 reported as centered.
- **IOL centration:** 100% reported with IOL intracapsular fixation and centered.

Clinical Findings:

- Mean BCVA at 1 month was 20/20 (Snellen equivalent to ETDRS assessment).
- No capsular abnormalities reported.
- No clinically significant slit lamp exam findings reported.

Diameter of Anterior Capsulotomy:

- Mean diameter of ZeptoTM capsulotomies = 5.14 mm +/- S.D. 0.14 mm (median = 5.2 mm; range 4.9-5.5 mm).

Minimum Incision Size

The minimum incision size required to accommodate the Zepto Handpiece tip is 2.2 mm. The minimum incision size used during the clinical study was 2.4 mm.

Conclusion of Nonclinical and Clinical Tests and Results

In conclusion, the data from this study, combined with the rigorous lab, preclinical testing and OUS clinical experience demonstrate that the Mynosys Zepto™ Capsulotomy System is as safe and effective as the legally marketed predicate with which it is compared for regulatory purposes and is therefore substantially equivalent.