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 17, 2015

MedDev Corporation
Ms. Eileen Ho
730 North Pastoria Ave.
Sunnyvale, CA 94085

Re: K150986
Trade/Device Name: Contour™ Eyelid Weight Implants
ThinProfile™ Eyelid Weight Implants
Regulation Number: 21 CFR 886.5700
Regulation Name: Implantable Eyelid Weight
Regulatory Class: Class II
Product Code: MML
Dated: July 8, 2015
Received: July 9, 2015

Dear Ms. Ho:

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" (21CFR 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,

Kesia Y. Alexander -A

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)*
K150986

Device Name
Contour Eyelid Weight Implants
ThinProfile Eyelid Weight Implants

Indications for Use *(Describe)*
The MedDev Contour and ThinProfile Eyelid Weight Implants are designed for the gravity-assisted treatment of protracted or permanent lagophthalmos, usually resulting from facial paralysis.

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."

510(k) Summary

A. Device Information:

Category	Comments
Sponsor / Submitter:	MedDev Corporation 730 North Pastoria Ave Sunnyvale, CA 94085 Contact: Patrick Grey, COO 408-730-9702 Pat@meddev-corp.com
Correspondent Contact Information:	Eileen Ho MedDev Corporation 730 North Pastoria Ave Sunnyvale, CA 94085 408-730-9702 eho@meddev-corp.com
Device Common Name:	Implantable Eyelid Weight
Device Classification Number:	21 CFR 886.5700 Eyelid Weight
Device Classification & Product Code:	Class II MML
Device Proprietary Name:	Contour™ Eyelid Weight Implants ThinProfile™ Eyelid Weight Implants

Predicate Device Information:

Predicate Device:	Contour Eyelid Implant Weights
Predicate Device Manufacturer:	MedDev Corp
Predicate Device Common Name:	Implantable Eyelid Weights
Predicate Device Premarket Notification #	K011740
Predicate Device Classification:	21 CFR 886.5700
Predicate Device Classification & Product Code:	Class II, MML

B. Date Summary Prepared
05 August 2015

C. Description of Device
MedDev *Contour*™ and *ThinProfile*™ Eyelid Weight Implants were designed for the treatment of lagophthalmos, i.e. the inability of the eyelid to fully close. This condition is typically due to a degree of facial paralysis.

The MedDev *Contour*™ and *ThinProfile*™ Eyelid Weight Implants are passive implants surgically placed in the eyelid. The density of their construct material (pure gold or platinum) provides the weight necessary to close the eyelid over the eye. The patient can

use their functional orbital musculature to keep their eyes open, but have the gravitational assist from the Implant to close the eyelid.

Contour™ Eyelid Weight Implants
Contour™ Eyelid Weight Implants feature a proprietary three-dimensional design that conforms to the curvature of the ocular globe. They are sized according to weight from 0.6g to 2.8g. They all have suture holes to assist in implantation.

ThinProfile™ Eyelid Weight Implant
MedDev's ThinProfile™ Eyelid Weight Implants are thinner than the Contour™ implants. The ThinProfile's reduced thickness provides improved eyelid cosmesis while providing the same effectiveness as our proven Contour™ implant. The ThinProfile™ Eyelid Weight Implant features a proprietary three-dimensional curvature. They are sized according to weight from 0.6g to 1.8g. They all have suture holes to assist in implantation.

D. Indications for Use
The MedDev *Contour*™ and *ThinProfile*™ Eyelid Weight Implants are designed for the gravity-assisted treatment of protracted or permanent lagophthalmos, usually resulting from facial paralysis.

E. Comparison to Predicate Device
The MedDev *Contour*™ and *ThinProfile*™ Eyelid Weight Implants are substantially equivalent in intended use, indications for use, technology, design, and materials as the predicate MedDev *Contour*™ Design Eyelid Implants (K011740).

The application and predicate devices have IDENTICAL product codes, Indications for Use, construction materials (99.99% gold or platinum) and design. They are implanted in an identical manner. They are all moist-heat sterilized and sold in sterile packaging.

The application implants have MR conditional labeling derived from the testing described below. The addition of MR conditional labeling does not raise any new questions of safety and efficacy.

The application devices meet all the requirements of the Special Controls initiated for these devices as published in the Federal Register (Vol 79, Num 76, pages 22012 – 16) on April 21, 2014.

Characteristic	Predicate: MedDev Contour™ Design Gold Eyelid Implants (K011740)	Application Device: MedDev *Contour*™ and *ThinProfile*™ Eyelid Weight Implants	How do differences, if any, pertain to justification of substantial equivalence?
Indications for Use	The Indications for Use of the proposed Contour Design Gold Eyelid Implants is exactly the same as for the original Contour Design Gold Eyelid Implants. The broad indication for prescribing MedDev's Contour Design Gold Eyelid Implants is for the gravity-assisted treatment of protracted or permanent lagophthalmos, usually resulting from facial paralysis. Conditions, which may damage the facial nerve, include Bell's palsy, facial nerve injury, trauma, tumor invasion, and resection of tumors, i.e. acoustic neuroma and parotidectomy.	The MedDev *Contour*™ and *ThinProfile*™ Eyelid Weight Implants are designed for the gravity-assisted treatment of protracted or permanent lagophthalmos, usually resulting from facial paralysis.	Differences in marketing names and grammatical construction of the statement. These differences have no impact on the substantial equivalence of the Indications for Use
FDA Product Code	MML	MML	Identical
Operating Principle (Technology)	Implants provide the additional weight needed to close the eyelid when the orbital musculature is compromised by facial paralysis.	Implants provide the additional weight needed to close the eyelid when the orbital musculature is compromised by facial paralysis.	Identical

Characteristic	Predicate: MedDev Contour™ Design Gold Eyelid Implants (K011740)	Application Device: MedDev *Contour*™ and *ThinProfile*™ Eyelid Weight Implants	How do differences, if any, pertain to justification of substantial equivalence?
Design			
Contour Model	1.0mm thickness 12.7mm spherical radius 1.0mm diameter suture holes 0.6 to 2.8g in 0.2g increments	1.0mm thickness 12.7mm spherical radius 1.0mm diameter suture holes 0.6 to 2.8g in 0.2g increments	Identical
ThinProfile Model	1.0 mm thickness 12.7mm spherical radius 1.0mm diameter suture holes Au: 0.6 to 1.6g in 0.2g increments Pt: 0.6 to 1.8g in 0.2g increments	*Contour*™ 1.0 mm thickness *ThinProfile*™ 0.65 mm thickness 12.7mm spherical radius 1.0mm diameter suture holes Au: 0.6 to 1.6g in 0.2g increments Pt: 0.6 to 1.8g in 0.2g increments	Identical. The ThinProfile™ Model was considered a non-significant change addition (per FDA memo K97-1) to K011740
Materials (body contacting)	Pure (99.99%) Gold or Platinum	Pure (99.99%) Gold or Platinum	Identical
MRI Compatible?	Yes, but not labeled as such	Yes	This submission documents that the predicate version of the device was MR compatible. Therefore the addition of MR compatible labeling has no bearing on the substantial equivalence of the predicate and application devices.

Characteristic	Predicate: MedDev Contour™ Design Gold Eyelid Implants (K011740)	Application Device: MedDev *Contour*™ and *ThinProfile*™ Eyelid Weight Implants	How do differences, if any, pertain to justification of substantial equivalence?
Permanent or Temporary Use?	Both	Both	Identical
Sterilization	Moist Heat Sterilized	Moist Heat Sterilized	Identical

F. Summary of Supporting Data

This premarket notification is being submitted to provide FDA clearance for MR conditional labeling and to demonstrate compliance with the new Special Controls for implantable eyelid weights. No other changes from the predicate to the application device are being made. As a result only biocompatibility, sterility, shelf-life and MR compatibility data are necessary to demonstrate substantial equivalence.

i. MRI Safety Review

To support the claim of "MR-Conditional," the testing demonstrated that the implants are conditionally safe when exposed to a static magnetic field of 3-Tesla or less. MR safety testing was conducted with the Gold and Platinum Contour™ Eyelid Weight Implants in the largest available sizes of 2.8g.

a. MRI Related force

MRI Related force testing was conducted using a method similar to ASTM F2052-06:2006, (a 3-Tesla (T) GE Excite MRI scanner at a location where the spatial gradient is 720 gauss/cm and the field strength is 2.7 T), which showed a 2° deflection for both the gold and platinum samples. Torque testing was conducted using a test apparatus with the Eyelid Implant, (2.8g Gold and Platinum Contour™ Eyelid Weight Implants), positioned in the center of the MR system. The Eyelid Implant was directly observed for possible movement with respect to the alignment of rotation relative to the static magnetic field of the 3-Tesla MR system. The following qualitative scale of torque was applied to the results: 0 (no torque) up to +4 (very strong torque). A result for the 2.8g Gold and Platinum Contour™ Eyelid Weight Implants in both the long and short axis was 0.

b. MRI Related Heating

MRI Related Heating evaluation was conducted using methods outlined in ASTM F2182-11a, "Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging." The Eyelid Implant with thermometry probes attached was placed in the gel-filled phantom. The implant test assembly was exposed to a 3-Telsa field for 15 minutes with temperatures recorded in 4-second intervals. The resulting maximum measured temperature change for the 2.8g Gold Contour™ Eyelid Weight Implant was +2.0° C. For the 2.8g Platinum Contour™ Eyelid Weight Implant the maximum was +2.3° C.

c. MRI Related artifact

MRI Related artifact testing was conducted using methods outlined in ASTM F2119-07, "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants". The 2.8g Gold and Platinum Contour™ Eyelid Weight Implants were tested separately. Each Eyelid Implant was subjected to a 3-Tesla MR system and pulse sequences commonly used for MR imaging. For the Gold 2.8g Contour™ Eyelid Weight Implant

the image artifact extends approximately 5-mm from the device when imaged using a gradient echo pulse sequence and a 3-Telsa MR system. For the Platinum 2.8g Contour™ Eyelid Weight Implant the image artifact extends approximately 10-mm from the device when imaged using a gradient echo pulse sequence and a 3-Telsa MR system.

ii. Biocompatibility

Biocompatibility of the Gold and Platinum Contour™ and ThinProfile™ Eyelid Weight Implants was established by a review of existing data and test results. The materials used in the implants and materials used in the manufacturing processes were reviewed for available toxicity and bioavailability data for each chemical component, and a justification for the tests conducted to evaluate all potential toxic end points was completed. Implant materials testing included Cytotoxicity MEM Elution test along with a Chemical Characterization of Materials (leachable test). The Cytotoxicity MEM Elution testing was conducted in accordance with:

- ISO 10993-1:2003 "Biological evaluation of medical devices -- Part 1: Evaluation and testing"
- ISO 10993-5:1999 "Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity"
- ISO 10993-12:2007 "Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials"
- United States Pharmacopeia 32 & National Formulary 27. 2009. <87> Biological Reactivity Tests, In Vitro
- United States Pharmacopeia 32 & National Formulary 27. 2009. <1031> The Biocompatibility of Materials Used in Drug containers, Medical Devices, and Implants
- Nelson Labs SOP STP0032 R4 (2009) MEM Elution

The leachable test and the inductively-coupled plasma atomic emission spectrometer (ICP-AES) analysis were conducted in accordance with:

- ANSI/AAMI/ISO 10993-12:2012 "Biological evaluation of medical devices – Part 12: Sample preparation and reference materials"
- ANSI/AAMI/ISO 10993-17:2012 "Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances"
- ANSI/AAMI BE83:2006 (R2011). Part 18: "Chemical characterization of materials"
- Nelson Labs SOP STP0181 R2 (2015)– Chemical Characterization of Materials
- ASTM E1097-12 "Standard Guide for Determination of Various Elements by Direct Current Plasma Atomic Emission Spectrometry"
- METL SOP QA manual 11.0-CHE1/ CHE11

The final report concludes that the MedDev Eyelid Weight Implants are biocompatible as defined by ISO 10993-1:2009.

iii. Sterility and Shelf-life

Sterilization validation and packaging validation (shelf life) were completed in accordance with ISO 11607:2006 "Packaging for Terminally Sterilized Medical Devices" and in context of ISO 13485:2003 "Medical devices — Quality management systems"

a. Sterilization

Sterilization validation was completed in accordance with ANSI/AAMI/ISO 17665-1:2006 "Sterilization of health care products-Moist heat-Part1: Requirements for the development, validation, and routine control of a sterilization process for medical devices" which demonstrates that the devices could be moist heat sterilized to a Sterility Assurance Level of 10^{-6}. The validation approach was based on the use of biological indicators (BI Spore Strips) in a half-cycle "overkill" method. The validation protocol includes an installation, operational, and performance qualification; and the demonstration of sterility assurance.

b. Shelf life

The shelf life testing included real time aging, distribution simulation, visual inspection, bubble leak testing, and seal strength testing. The shipping configuration and packaging integrity were tested at the completion of real-time aging of 36 months in accordance with:

- ASTM D4169-05 "Standard Practice for Performance Testing of Shipping Containers and Systems"
- ASTM F1886-98 "Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection"
- ASTM F2096-04 "Standard Test Method for Detecting Gross leaks in Medical Packaging by Internal Pressurization (Bubble Test)"
- ASTM F88-06 "Standard Test Method for Seal Strength of Flexible Barrier Materials"

Other reviews included:

- Seal Strength Test Capability index study
- A review of product's functionality and examination for physical damage at the completion of the packaging integrity testing
- Testing and validation of the microbial barrier performance for Tyvek®, manufactured by DuPont™, demonstrate an effective barrier for up to five years. Testing standards used by DuPont™:
  - ASTM F1608-00(2009) "Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)"

- ASTM F2638-12 “Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier”

The completed testing confirmed the integrity of the sterile barrier and packaging for a period of 36 months.

G. Conclusion Statement

MedDev concludes that the application and predicate Eyelid Implants are substantially equivalent.