DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 6, 2017

Altomed Limited
Stuart March
2 Witney Way
Boldon Business Park
Tyne & Wear NE35 9PE England

Re: K170591
Trade/Device Name: Altomed Malhotra Platinum Segments
Regulation Number: 21 CFR 886.5700
Regulation Name: Eyelid weight
Regulatory Class: Class II
Product Code: MML
Dated: March 17, 2017
Received: March 20, 2017

Dear Stuart March:

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)*

Device Name
Altomed Malhotra Platinum Segments

Indications for Use *(Describe)*

Malhotra Platinum Segments are eyelid implants designed for the gravity-assisted treatment of lagophthalmos.

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.

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510(k) Summary, K170591:

1. Submitter/510(k) Owner:

Altomed Limited
2 Witney Way, Boldon
Tyne and Wear, England, NE35 9PE
Contact Person: Stuart March
Tel: (0) 191 519 0111
Fax: (0) 191 519 0283
Date prepared: June 1, 2017

2. Device:

Device Proprietary Name: **Malhotra Platinum Segments**
Device Common Name: Implantable Eyelid Weight
Classification: Class II
Classification Name: Implantable Eyelid Weight
Product Code: MML

3. Predicate Device: K011115, Heinz Kurz Platinum Implants

4. Device Description:

Sterile, single use, eyelid weight implant segments, used to treat Lagophthalmos to weigh down the upper eye lid to aid closure, used in combinations to achieve optimum result for each patient. The devices are made of 90% platinum 10% iridium, an industry standard alloy utilized for eyelid implants. The segments are rectangular in shape, contoured to the shape of the eye, with suture holes for both linking segments together in a chain and securing segments into position. Two sizes of segments are provided, with total weight customized for patient need by surgeon selection of segment combinations. The min/max combination range is from total 0.4g to total 2.0g. They achieve their intended purpose through gravity, weighing down the upper eyelid.

5. Indications For Use:

Malhotra Platinum Segments are eyelid implants designed for the gravity-assisted treatment of lagophthalmos.

6. Technological Characteristics and Substantial Equivalence:

The Malhotra Platinum Segments have the same intended use and similar technical characteristics to the predicate device. Both devices are intended for treatment of lagophthalmos, assisting eyelid closure by the addition of weights implanted into the upper eyelid. Both devices are made from a 90%/10% platinum/iridium alloy. They are similar in shape and size, customizable by the surgeon according to patient need and fixed into place with sutures. While the predicate device comes in a range of sizes, the Malhotra Platinum Segments are used in customized combinations to achieve the desired size. Both are provided sterile. The Malhotra Platinum Segments are sterilized with ethylene oxide. EO residuals have been determined to be well below established limits for implanted medical devices; therefore, this difference in technological characteristic raises no new issue of safety.

Characteristics	Subject Device	Predicate Device	Comparison
Trade Name	**Malhotra Platinum Segments**	**Heinz Kurz Platinum Implants**	
510(k) Number	**TBD**	**K011115**	
FDA Product Code	**MML**	**MML**	Equivalent
Indications for use	Gravity-assisted treatment of lagophthalmos.	Treatment of lagophthalmos by optimization of lid closure through addition of weight to upper lid.	Equivalent meaning
Anatomical site, exposure duration	Eyelid implant, permanent	Eyelid implant, permanent	Equivalent
Principle of operation	Implants provide the additional weight needed to close the upper eyelid when the orbital musculature is compromised by facial paralysis.	Implants provide the additional weight needed to close the upper eyelid when the orbital musculature is compromised by facial paralysis.	Equivalent
Technique for application	Surgeon determines appropriate weight. Segment implants are surgically inserted and sutured together and into place. Surgically reversible.	Surgeon determines appropriate weight. Implants are surgically inserted, sutured into place. Surgically reversible.	Equivalent
Sizes/description	Rectangular, shaped to fit curvature of the eyeball, comes in 2 sizes. Designed to be used in custom combinations to achieve desired weight, with max of 2.0g: A7080: 6.00mm x 2.30mm x 1.00mm; 0.2g; curved, 3 suture holes 0.95mm in diameter A7082: 6.00mm x 4.00mm x 1.00mm; 0.4g; curved, 4 suture holes 0.95mm in diameter	Rectangular, shaped to fit curvature of the eyeball. Sizes vary from: • 0.6 to 2.2g in 0.2g increments; • 15mm x 5mm to 20mm x 5.2mm, with 4 suture holes.	Same basic shape and weight range covered.
Materials	90% Platinum, 10% Iridium	90% Platinum, 10% Iridium	Equivalent
MRI Compatibility	MR Conditional	MR Conditional	Equivalent
Sterility	Ethylene Oxide Sterilized, SAL 10^{-6}	Gamma Sterilized, SAL 10^{-6}	Same Sterility Assurance Level; low EO residuals raise no new questions of safety.

7. Performance Data:

a) Biompatibility Testing:

Biocompatibility evaluation conducted on the Malhotra Platinum Segments shows the suitability of materials permanently exposed to tissue. Both implant material and materials used in the manufacturing process were reviewed. Standards relevant to the evaluation are BS EN ISO 10993-1:2009, Biological evaluation of medical devices Part 1 Evaluation and testing, and BS EN ISO 10993-18:2009, Biological evaluation of medical devices Part 18, Chemical characterization of materials.

The material used in this medical device is a clinically established material for use in invasive applications, and is the identical material used in the predicate device, which has been on the market since 2001: platinum/iridium alloy, 90%/10%.

BS EN ISO 10993-18:2009 identifies that a documented qualitative description of the composition of the finished device, including additives and processing residues for each material used, is required as part of the determination of material equivalence. Compositional analysis of the Malhotra Platinum Segments has been performed using x-ray fluorescence and induction coupled plasma techniques. Safety information for the processing materials has been obtained and evaluated.

Ethylene Oxide does not alter the biocompatibility of the Malhotra Platinum Segments as they are made of metal, are very small, do not have grooves or cavities, and therefore not highly retentive of EO residuals. EO Residuals for the Platinum Segments have been determined to be well within acceptable levels as specified in ISO 10993-7.

Paragraph 6.1 (material characterization) of BS EN ISO 10993-1:2009 states that if the combination of all materials, chemicals and processes has an established history of safe use in the intended application, then further characterization and biological evaluation might not be necessary. The material used in this medical device is a clinically established material for use in invasive applications, and is identical to the material used in the predicate device, having a toxicological or biological safety no worse than that of the predicate.

b) Sterility and Shelf Life:

Sterilization validation was completed according to ISO 11135-1:2007, *Sterilization of health products – Ethylene Oxide – Requirements for development, validation and routine control of a sterilization process for medical devices*. The Half-Cycle Method test results demonstrated EO sterilization to a Sterility Assurance Level of 10^{-6}. Validation is repeated yearly.

A five-year shelf life was validated using real-time aging, shipping, visual inspection, dye leak tesing, and seal strength testing. Test results demonstrated that package integrity and product sterility are maintained over the stated five-year shelf life. Tests were completed according to:

- Visual Seal Integrity Inspection (ASTM F1886 / F1886M-09, 2013)
- Package burst strength (ASTM F1140/F1140M-13)
- Package Dye Leak Test (ASTM F1929-12)

c) MR Compatibility:

MRI Compatibility testing according to recognized standards was undertaken to determine magnetic field interactions, heating, and image artifacts for the Malhotra Platinum Segments to support the claim of "MR Conditional." Worst-case product configuration and positioning for MRI-related heating was determined. Testing demonstrated that the implants are conditionally safe when exposed to a magnetic field of 3-Tesla or less.

i. MRI Related force

For the assessment of translational attraction, a deflection angle test was conducted. A 3-Tesla (GE Excite) active-shielded, MRI scanner was used for the assessments of magnetic field interactions. The Malhotra Platinum Segment was attached to a special non-metallic, test apparatus to measure the deflection angle in the MR system. The finding for translational attraction for the Malhotra Platinum Segment was 2-degrees.

Torque testing was conducted with the Malhotra Platinum Segment on a test apparatus positioned in the center of the MR system. The Malhotra Platinum Segment was directly observed for possible movement with respect to alignment or 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). The qualitatively measured torque at 3-Tesla for the Malhotra Platinum Segment was 0, no torque.

ii. MRI Related Heating

MRI-related heating evaluation at 1.5-Tesla/64-MHz in worst-case positioning indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than 2.0°C. The result for testing at 3-Tesla/128-MHz indicated that the greatest amount of heating was equal to or less than 1.5°C

iii. MRI Related artifact

MRI Related artifact testing for both echo pulse and echo spin sequences was conducted. The gradient echo pulse sequence produced larger artifacts than the T1-weighted, spin echo pulse sequence for the device. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10-mm relative to the size and shape of the Malhotra Platinum Segment.

8. Conclusion:

The Malhotra Platinum Segment device is substantially equivalent to the predicate devices based on having the same intended use and similar technological characteristics. Minor differences in technological characteristics, size configuration and sterilization method, do not raise new issues of safety or efficacy. Performance data demonstrate sterility, shelf life, biocompatibility, and compatibility in a magnetic resonance environment.