June 11, 2021

FCI (France Chirurgie Instrumentation) SAS
% Dennis Hahn, RAC
Clinical Research Consultants, Inc.
3308 Jefferson Avenue, Upper Level
Cincinnati, OH 45220

Re: K203569
Trade/Device Name: Gold Tapered Weight Eyelid Implants, Platinum Tapered Weight Eyelid Implants
Regulation Number: 21 CFR 886.5700
Regulation Name: Eyelid Weight
Regulatory Class: Class II
Product Code: NCB
Dated: April 30, 2021
Received: May 5, 2021

Dear Dennis Hahn:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LT Charles Chiang
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203569

Device Name
Gold Tapered Weight Eyelid Implant
Platinum Tapered Weight Eyelid Implant

Indications for Use *(Describe)*
Gold and Platinum Tapered Weight Eyelid Implants are intended 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.

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K203569

510(k) Summary as required by 21 CFR§807.92(c)

510(k) Owner: France Chirurgie Instrumentation SAS (FCI S.A.S.)
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Date: June 10, 2021

Trade Name:	Gold Tapered Weight Eyelid Implants Platinum Tapered Weight Eyelid Implants
Common name:	Implantable Eyelid Weights
Device Classification Regulation:	886.5700 – Eyelid Weights
Classification Product Code:	NCB – Weights, Eyelid, Implantable

Identification of a Legally Marketed Predicate Device

The FCI Gold and Platinum Tapered Weight Eyelid Implants are substantially equivalent to the Contour™ and ThinProfile™ Eyelid Weight Implants marketed by MedDev Corporation, 510(k) Premarket Notification Number: K150986, FDA Classification Product Code MML.

The following are included as reference devices for the purpose of sterilization and biocompatibility evaluation:

K011740: Contour Gold Eyelid Weight Implants (MedDev Corporation)
K983607: Labtician Lid Load Gold Eyelid Weight Implants (Labtician Ophthalmics, Inc.)
K000127: Kurz Pure Gold Upper Eyelids Implant (Oberascher), Model 4001 02-4001 10 (HEINZ KURZ GMBH MEDIZINTECHNIK
K170591: Altomed Malhotra Platinum Segments (Altomed Limited)

K011115: Kurz Upper Eyelid Implant- Platinum/Iridium,Models Regular 4007 003-007, Special 4007 002, 4007 008-010 (HEINZ KURZ GMBH MEDIZINTECHNIK)

General Description

The Gold and Platinum Tapered Weight Eyelid Implants are implantable devices for the gravity-assisted treatment of lagophthalmos by the addition of weight to the upper eyelid. The device is made of either 99.99% purity gold or platinum. Platinum devices can be implanted in patients who are allergic to gold. The Gold and Platinum Tapered Weight Eyelid Implants come in two thicknesses (thin and normal profiles) and in seven different weights ranging from 0.6 g to 1.8 g (in 0.2 g increments). The Gold and Platinum Tapered Weight Eyelid Implants are each provided as a sterilized product.

MRI Safety Information:
The Gold and Platinum Tapered Weight Eyelid Implants are "MR Conditional". A patient with this device can be safely scanned in an MR system meeting the following specific conditions:

- Static magnetic field of 3 Tesla or less;
- Maximum spatial gradient magnetic field of 4,000 Gauss/cm (extrapolated) or less;
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system;
- Under the scan conditions defined about, the Gold Tapered Weight Eyelid Implant is expected to produce a maximum temperature rise of 2.0°C after 15 minutes of continuous scanning (i.e., per pulse sequence);
- Under the scan conditions defined about, the Platinum Tapered Weight Eyelid Implnt is expected to produce a maximum temperature rise of 2.3°C after 15 minutes of continuous scanning.

Scanning in an MR system without meeting above-mentioned conditions could endanger the patient.

In non-clinical testing, the image artifact caused by the Gold and Platinum Tapered Weight Eyelid Implants extends respectively 5mm and 10mm from the device when imaged using a gradient echo pulse sequence and a 3 tesla MR system.

Indications for Use

Gold and Platinum Tapered Weight Eyelid Implants are intended for the gravity-assisted treatment of protracted or permanent lagophthalmos, usually resulting from facial paralysis.

Comparison of Technological Characteristics

The FCI Gold Tapered Weight Eyelid Implants and Platinum Tapered Weight Eyelid Implants are identical, or nearly identical, in every respect to the MedDev Contour™ and ThinProfile™ Eyelid Weights except for the sterilization method. The FCI devices are sterilized by ethylene oxide, whereas the MedDev devices are sterilized by moist heat (steam). Both sterilization methods sterilize to SAL 10^{-6}, and the finished devices are each provided as sterile products for permanent implantation in the eyelid for gravity-assisted treatment of lagophthalmos.

The cited reference devices [Labtician Lid Load Gold Eyelid Weight Implants (K983607), Kurz Pure Gold Upper Eyelids Implant (K000127), Altomed Malhotra Platinum Segments (K170591), and Kurz Upper Eyelid Implant- Platinum/Iridium,Models (K011115)] are all sterilized by ethylene oxide.

The FCI and predicate MedDev eyelid weight implants are each manufactured from 99.99% purity gold or from 99.99% purity platinum and are available in seven different weights ranging from 0.6g to 1.8g (in 0.2 g increments). The 99.99% purity gold and platinum materials used in each device are medical grade with well characterized mechanical and biocompatibility properties.

The following table summarizes the similarities and differences between the FCI and MedDev predicate device:

Aspect	**Subject Device** Gold and Platinum Tapered Weight Eyelid Implants	**Primary Predicate** MedDev Corporation Contour™ and ThinProfile™ Eyelid Weight Implants (K150986)	**Comments**
Similarities			
Intended use	Gravity-assisted treatment for lagophthalmos	Gravity-assisted treatment for lagophthalmos	Identical
Indications for use	GOLD AND PLATINUM EYELID WEIGHT IMPLANTS are intended for the gravity assisted treatment of lagophthalmos, usually resulting from facial paralysis.	MedDev Contour™ and ThinProfile™ Eyelid Weight Implants are designed for the gravity-assisted treatment of protracted or permanent lagophthalmos, usually resulting from facial paralysis.	Identical
Type of device	Gold or platinum eyelid weight	Gold or platinum eyelid weight	Identical
Material	99.99% Purity Gold	99.99% Purity Gold	Identical

Aspect	Subject Device Gold and Platinum Tapered Weight Eyelid Implants	Primary Predicate MedDev Corporation Contour™ and ThinProfile™ Eyelid Weight Implants (K150986)	Comments
	99.99% Purity Platinum	99.99% Purity Platinum	Identical
Sizes	Available in 7 sizes, 0.6 g to 1.8 g, in 0.2 g increments.	Available in 7 sizes, 0.6 g to 1.8 g, in 0.2 g increments. Contour is also available in larger sizes (2.0-2.8 g).	Identical for standard sizes.
MR Compatibility	MR Conditional	MR Conditional	Identical
Single-Use Only	Yes	Yes	Identical
Differences			
Sterile unit package	Packaged in double PETG blister with Tyvek lid.	Packaged in double pouch with Tyvek and PET lidding.	Different packaging configuration, similar materials.
Sterilization method	Ethylene Oxide	Moist Heat	Different, both methods sterilize to SAL of 10^{-6}.

Special Controls

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

Brief Summary of Non-Clinical Tests and Results

The following summarizes the testing conducted to address MR compatibility, biocompatibility, sterilization and shelf life for the Gold and Platinum Tapered Weight Eyelid Implants.

1. 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 Eyelid Weight Implants in the largest sizes available in the market 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), 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 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 Eyelid Weight Implant was +2.0° C. For the 2.8g Platinum 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 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 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 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.

2. Biocompatibility

Biocompatibility of the Gold and Platinum Tapered Weight Eyelid 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 a chemical characterization

of materials (leachable test) and cytotoxicity testing. Biocompatibility testing was conducted in in accordance with:

ISO 10993-1:2009	*Biological evaluation of medical devices – Part 1: evaluation and tests*
ISO 10993-5:2009	*Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity*
ISO 10993-18:2020	*Biological evaluation of medical devices -- Part 18: Chemical Characterization of Medical Device Materials in a Risk Management Process*

3. Sterility and Shelf-life

a. Sterilization

The Gold and Platinum Tapered Weight Eyelid Implants are distributed as a packaged, sterile device. The Gold and Platinum Tapered Weight Eyelid Implants are sterilized by ethylene oxide (EO) in the sealed packaging (double Tyvek blister). EO is an established Category A Method, in accordance with ISO 11135-1:2007 *Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.* A summary of the sterilization and sterilizer information required for 510(k) submissions for devices labeled as sterile per the FDA *Guidance for Industry and Staff: Submission and Review of Sterility Information* is provided below.

Sterilization Method	Ethylene Oxide
Contract Sterilization Site	STERLAB 2720 chemin Saint Bernard Vallauris, France 06224 Establishment Registration Number: 1000286794
Sterilization Chamber and Cycle	FCI products are sterilized in STERLAB's fixed cell N°6 with cycle C6-S073 dedicated to FCI products.
Maximum Levels of Sterilant (EO) Residuals	Ethylene Oxide (EO) 4.0µg/device Ethylene chlorohydrin (ECH) 5.8 µg /device
Bioburden Specification	< 100 CFU/device
Validation Method	Half-cycle
Minimum Aeration Time	5 Days
Sterility Assurance Level	10^{-6}
FDA Recognized Standards Applied	AAMI/ANSI/ISO 10993-7 - *Biological Evaluation of Medical Devices – Part 7:Ethylene Oxide Sterilization Residuals*. ISO 11135-1:2007 - *Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* ISO 11138-1:2006 - *Sterilization of health care products -- Biological indicators -- Part 1: General requirements* ISO 10993-7:2008 - *Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals*

b. Shelf life

Shelf life of the Gold and Platinum Tapered Weight Eyelid Implants has been established at five years based on accelerated aging. The functional performances of the device (dimensional and visual inspection) have been verified through the tests conducted before and after the aging; the device transport testing was conducted in accordance with the standard ISTA 3A, and package integrity (visual integrity, peel strength, dye penetration and bubble leak test) was conducted. Package integrity testing was conducted in accordance with:

ASTM F1929-15:2015 - *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*

ASTM F1886-16:2017 - *Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection*

ASTM F88/F88M15:2016 - *Test Method for Seal Strength of Flexible Barrier Materials*

ASTM F2096-11: 2019 - *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)*

Basis of Substantial Equivalence

The FCI Gold and Platinum Tapered Weight Eyelid Implants are substantially equivalent to the MedDev Contour™ Eyelid Weight Implants and ThinProfile™ Eyelid Weight Implants in intended use and indications for use, basic design concept, materials (gold and platinum), dimensions, and manufacturing processes, with the primary difference being that the FCI Gold and Platinum Tapered Weight Eyelid Implants are sterilized by ethylene oxide; whereas, the predicate MedDev eyelid weight implants are sterilized by moist heat (steam), both of which sterilize to SAL 10^{-6}. The FCI Gold and Platinum Tapered Weight Eyelid Implants are manufactured by FCI and distributed in the U.S.A. by FCI Ophthalmics, Inc. The Contour™ Eyelid Weight Implants and ThinProfile™ Eyelid Weight Implants are manufactured and distributed in the U.S.A.by MedDev Corporation.