June 24, 2022

FCI (France Chirurgie Instrumentation) SAS
% Barbara Fant, PharmD
Principal Regulatory Consultant
Clinical Research Consultants, Inc.
3308 Jefferson Avenue, Upper Level
Cincinnati, Ohio 45220

Re: K212741
Trade/Device Name: EZYPOR
Regulation Number: 21 CFR 886.3320
Regulation Name: Eye Sphere Implant
Regulatory Class: Class II
Product Code: HPZ
Dated: May 12, 2022
Received: May 13, 2022

Dear Dr. Barbara Fant:

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,

Anjana Jain, PhD
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)*
K212741

Device Name
EZYPOR®

Indications for Use *(Describe)*
The EZYPOR® orbital implants are designed to fill the orbital cavity following enucleation, evisceration or during secondary implantation.

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.

510(k) Summary -- K212741

510(k) Owner: France Chirurgie Instrumentation SAS (FCI S.A.S.)
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Date: June 23, 2022

Trade Name: EZYPOR®

Common name: Orbital Implant

Classification Name: Implant, Eye, Sphere

Regulation Number: 886.3320

Product Code: HPZ

Identification of a Legally Marketed Predicate Device

EZYPOR® orbital implants are substantially equivalent to the MEDPOR® Plus SST™ Sphere (Smooth Surface Tunnel Sphere, 510(k) Premarket Notification Number K021357, FDA Product Code HPZ.

Identification of a Legally Marketed Reference Device

The MEDPOR® Sphere (K863943; Product Code HPZ) is a reference device for the technological characteristics of the 12 to 14 mm diameter porous, smooth spherical shape without a suture platform. The Silicone Orbital Implant (K911110) is a reference device for the technological characteristics of the 12 to 14 mm diameter spherical shape.

General Description

EZYPOR® orbital implants are high density polyethylene (UHMWPE) implants designed to fill the orbital cavity following enucleation, evisceration or during secondary implantation procedures. The polyethylene material has an open porosity structure of 40 to 60%. The implants are available in six diameter sizes, 12, 14, 16, 18, 20 and 22 mm.

EZYPOR® orbital implants are supplied sterile and are sterilized by ethylene oxide. A green indicator on the label shows that the product followed a sterilization cycle validated by FCI. The EZYPOR® orbital implants are sterilized in their final double-blister packaging, to make them easier to handle in aseptic conditions.

Indications for Use

The EZYPOR® orbital implants are designed to fill the orbital cavity following enucleation, evisceration or during secondary implantation.

Sterilization

The EZYPOR® Orbital Implants are distributed as a packaged, sterile device. The EZYPOR® Orbital Implants are sterilized by ethylene oxide (EO) in the sealed packaging. EO is an established Category A Method, in accordance with ISO 11135-1:2014 *Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.* Endotoxin testing was performed as one of the assessments to evaluate sterility for the EZYPOR® Orbital Implants.

Brief Summary of Non-Clinical Tests and Results

Non-clinical bench testing for the EZYPOR® orbital implants included evaluation of diameter and tunnel dimensions, implant mass, sphericity and open porosity, implant resistance to compression, and implant resistance to traction. All nonclinical test results met the predetermined acceptance criteria for the device. In-process controls and final product quality controls, including finished product release testing and inspection, assure that EZYPOR® is manufactured within specifications.

Biocompatibility of the EZYPOR® orbital 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), cytotoxicity testing, sensitization and irritation. Biocompatibility testing was conducted in in accordance with:

ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
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*

Shelf life of the EZYPOR orbital implants has been established at five years based on accelerated aging and package integrity. The functional performance of the device as well as the package integrity 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, dye penetration and bubble leak test) was conducted.

Basis of Substantial Equivalence

EZYPOR® orbital implants are substantially equivalent to the predicate MEDPOR® Plus SST™ Sphere (Smooth Surface Tunnel Sphere) cleared under K021357 as both devices have the same intended use and indications for use to fill the orbital cavity (void) following enucleation or evisceration of the eye. The EZYPOR® and MEDPOR® Plus SST™ Sphere orbital implants are both manufactured from porous polyethylene material that has the same pore size and porosity. The design of EZYPOR® and MEDPOR Plus SST™ predicate device are similar, with each having a spherical shaped body and available in diameters of 16 to 22 mm that have a suture platform which allows the device to be sutured to the muscularis. The EZYPOR® is also available in 12 mm and 14 mm diameter models that are designed without a suture platform. The EZYPOR® and MEDPOR devices are both sterilized by Ethylene Oxide.

The difference between the subject and predicate devices is that the EZYPOR® orbital implant is also available in 12 mm and 14 mm diameter sizes (without a suture platform), which is the same as the MEDPOR® Sphere; whereas the 16 mm is the smallest available diameter of the predicate device. The 12 mm and 14 mm diameter sizes of the EZYPOR® are equivalent in size to Silicone Orbital Implants (K911110) manufactured and sold by FCI.

The similarities and differences between the EZYPOR® orbital implants and the predicate and reference devices are presented in the comparison table below. Based on this comparison, EZYPOR® orbital implants are substantially equivalent to the MEDPOR® Plus SST™ Sphere (Smooth Surface Tunnel Sphere, 510(k) predicate device (K021357).

Comparison of EZYPOR®+and the Predicate Device and Reference Devices				
	EZYPOR®	**MEDPOR® Plus SST™ Sphere (Smooth Surface Tunnel Sphere) K021357 (Predicate Device)**	**MEDPOR® Sphere K863943 (Reference Device)**	**Silicone Orbital Implant K911110 (Reference Device)**
FDA Product Code	HPZ	HPZ	HPZ	HPZ
Mfg.	FCI S.A.S. FCI SUD	Stryker	Stryker	FCI S.A.S. FCI SUD
Intended use	To fill the orbital cavity following enucleation or evisceration	Orbital volume replacement implant	Orbital volume replacement implant	To fill the orbital cavity following enucleation or evisceration
Indications for Use	The EZYPOR® orbital implants are designed to fill the orbital cavity following enucleation, evisceration or during secondary implantation.	Void volume replacement following enucleation and/or evisceration of the eye.	For orbital reconstruction following enucleation and evisceration procedures.	Fill the orbital cavity following enucleation, evisceration
Patient Contact Materials	Porous, high-density polyethelene	Porous, high-density polyethylene	Porous, high-density polyethylene	Medical grade silicone
Pore Size	350-600 µm	350-600 µm	350-600 µm	Not applicable
Porosity	40 - 60 %	40 - 60 %		
Mfg. Process	Preformed shapes	Preformed shapes	Preformed shapes	Molded shape
Design				
Available Diameters	12, 14, 16, 18. 20, 22 mm	16, 18, 20, 22 mm	14 mm to 23 mm diameters	12 mm to 22 mm diameters
Single-Use Only	Yes	Yes	Yes	Yes
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide