FX Shoulder USA, Inc.
Kathy Trier
VP Regulatory, Quality, Clinical, Compliance
13465 Midway Road, Suite 101
Dallas, Texas 75244

February 16, 2021

Re: K201391
Trade/Device Name: Easytech® Anatomical Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PKC
Dated: January 14, 2021
Received: January 15, 2021

Dear Kathy Trier:

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,

Michael Owens
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K201391

Device Name
Easytech® Anatomical Shoulder System

Indications for Use *(Describe)*

The Easytech® Anatomical Shoulder System is indicated for use in total shoulder replacement to treat a severely painful and/or disabled joint resulting from osteoarthritis.

The humeral stemless of the Easytech® Anatomical Shoulder is intended for cementless use only. The glenoid components of the Easytech® Anatomical Shoulder System are intended for cemented use only.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional rotator cuff is necessary to use the device.

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

Applicant/Sponsor:	FX Shoulder USA, Inc. 13465 Midway Road, Suite 101 Dallas, Texas 75244 Establishment Registration No: 3014128390
Manufacturer:	FX Solutions SAS 1663 Rue de Majornas Viriat, France 01440 Establishment Registration No: 3009532798
Contact Person:	Kathy Trier, Ph.D. VP Regulatory, Quality, Clinical and Compliance
Date:	January 14, 2021
Proprietary Name:	Easytech® Anatomical Shoulder System
Common Name:	Anatomic Shoulder Prosthesis
Product Code(s):	PKC
Classification Name:	21 CFR 888.3660: shoulder joint metal/polymer semi-constrained cemented prosthesis – Class II
Substantially Equivalent Devices:	**Primary Predicate:** Arthrex Eclipse (K183194) **Reference Device:** Tornier Simpliciti™ Shoulder System (K143552) Humeris® Shoulder System (K163669)

Device Description

The Easytech® Anatomical Shoulder is an anatomical shoulder prothesis designed for use in patients with a functional rotator cuff. The Easytech® humeral stemless (Anchor base) is used with a connector, a centered or offset humeral head, and a glenoid for use in an anatomical shoulder configuration.

This system is designed to articulate with a glenoid component for total shoulder arthroplasty. Subject of this submission is the cementless, stemless Humeral Anchor base that is part of the Easytech® Anatomical Shoulder System. The compatible components to complete the system have been cleared previously in K111097, K123814, and K163669.

The Easytech® Anchor base is a stemless prosthesis. The cementless Anchor base is available in diameters of 30 to 38 mm. The Anchor base has a main central post with striaes. In the periphery of the Anchor base, five retentives striaes are positioned to

help with the primary fixation. The undersurface of the Anchor base, including the central post and retentive striaes, has a plasma sprayed CPTitanium and Hydroxyapatite coating without the superior surface and the female taper. The Anchor base incorporates a female taper for attachment of compatible components. This component is manufactured in Ti-6Al-4V ELI alloy conforming to ISO 5832-3.

The Anchor base can be used with a straight taper connector or a centered spacer manufactured from Ti-6Al-4V ELI alloy conforming to ISO 5832-3, a centered or offset humeral head manufactured from wrought Co-Cr-Mo alloy conforming to ISO 5832-12 and a 2 pegs or 3 or 4 pegs cemented glenoid manufactured from ultra high molecular weight polyethylene (UHMWPE) conforming to ISO 5834-2 for use in an anatomical shoulder configuration.

Intended Use / Indications
The Easytech® Anatomical Shoulder System is indicated for use in total shoulder replacement to treat a severely painful and/or disabled joint resulting from osteoarthritis.

The humeral stemless of the Easytech® Anatomical Shoulder is intended for cementless use only. The glenoid components of the Easytech® Anatomical Shoulder System are intended for cemented use only.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional rotator cuff is necessary to use the device.

Summary of Technologies / Substantial Equivalence
The Easytech® Anatomical Shoulder System is substantially equivalent to the primary predicate in that it has the same indications, comprised of the same materials, is similar in design and sizes. Both are provided sterile for single use using gamma irradiation. The subject device, primary predicate and reference devices conform to recognized performance standards for total shoulder devices. The design differences do not affect safety or effectiveness as demonstrated via mechanical testing to characterize the device (vs reference device K143552) and clinically via the Easytech Anatomic Retrospective Cinical Study. The coating of the subject device is identical to the coating of the reference device K163669. Differences between the subject device and the predicate devices do not raise new questions of safety and effectiveness.

Non-Clinical Testing
Static testing includes lever out, pull out, and torque out testing of the Anchor base and static and dynamic testing of the humeral component of the Easytech® Anatomical Shoulder System includes construct fatigue testing and post-fatigue fatigue pull off and torque out testing in accordance with ASTM F2009-00 (2011) Standard Test Method for Determining the Axial Disassembly Force of Taper Connection of Modular Prostheses. All samples reached 5,000,000 cycles with no failure or disassociation observed. There was no significant mass loss of the specimen tapers. Fretting and corrosion analysis has also been completed to assess the taper interface for signs of fretting scars, fretting or pitting corrosion and presence of corrosion byproducts. Samples were evaluated via SEM and qualitative energy dispersive x-ray spectroscopy (EDS) analysis of any corrosion products observed. Fretting and corrosion results were compared to the literature and did not raise new questions of safety. Range of Motion analysis was also completed. Characterization of the Ti/HA plasma spray coating was submitted in

previous submissions (K130759, K162455), is the same coating for the reference predicate (K163669), and is referenced to support the current submission. The results of these tests indicate that the performance of the Easytech® Anatomical Shoulder System is adequate for its intended use. Side-by-side mechanical testing vs reference predicate was completed for further characterization of the subject device.

Clinical Testing

The Easytech Anatomical Shoulder System Retrospective study was a single arm, multi-center study conducted at 5 sites in France as part of the manufacturer's post-market surveillance for its shoulder devices. A total of 141 patients were implanted with the study device during the period January 2015 to December 2016, seven (7) patients refused to share their data and five (5) had a diagnosis other than osteoarthritis. The purpose of the retrospective study was to demonstrate safety and effectiveness of the Easytech Anatomical Shoulder System for total shoulder arthroplasty at Month 24. This data is real world evidence and reflects clinical experience with the Easytech stemless anatomic shoulder as it is used by orthopaedic surgeons who have community and clinic based practices and who implanted osteoarthritic patients who are representative of their broad patient population.

One hundred twenty-nine (129) patients having a primary diagnosis of osteoarthritis were analyzed and had an average length of follow-up of 3 years. A subject was a success at 24+ months if: the Adjusted Constant Score was $\geq$54 and improved from baseline $\geq$10, there was no migration or subsidence, radiolucencies of the humeral or glenoid components and implant integrity was maintained, Adjusted Constant Scorethey did not have revision surgery, and they did not have a serious adverse device event. Secondary objectives included range of motion, radiograph review for osteolysis,anatomic fracture and other observations, other adverse event and device survival. Patient outcomes were compared to the performance goal based upon the primary predicate device clinical trial.

The percentage of subjects who met all four criteria is 91.7% with a lower two-sided 90% confidence bound of 87.3%. As the lower bound is greater than the percentage of success observed in the performance goal of the predicate IDE (92.3% and the reference margin (10%), the null hypothesis is rejected in favor of the alternative hypothesis, that the Easytech Anatomical Shoulder System meets the performance goal and is a study clinical success.

The average Month 24+ Adjusted Constant Score was 99.14 (SD 18.73) with a clinically significant improvement ($p < 0.0001$) from preoperative baseline of 55.68 (SD 18.50). Ninety-nine percent (99.0%) of Easytech patients achieved Adjusted Constant Score success.

Range of motion also showed significant improvement from preoperative to postoperative ($p < 0.0001$).

Independent radiograph review reported no migration or subsidence of humeral or glenoid components, no radiolucencies, no anatomic fractures, and no issues with implant integrity.

There were eight (8) reported serious adverse device effects (SADE) occurring in 8 study patients. Four (4) were for anatomic instability which was caused by either a trauma or glenoid dysplasia. Three (3) were for dislocation, two (2) of which occurred within or at the first month postoperative. One (1) was for glenoid loosening. Seven (7) resulted in a secondary surgical procedure with five (5) of them converting the anatomic construct to a reversed shoulder without removal of the well-fixed, stable Anchor base. One (1) dislocation was reduced under general anesthesia and no device components were revised. One (1) dislocation resulted in the revision of the Anchor base due to the humeral cut during the index surgery. The clinical success of the Anchor base is 99.2%.

Survival analysis for the Easytech Anatomical Shoulder System demonstrates 95% survivorship at an average 3 years follow-up.

Conclusions

The Easytech Anatomical Shoulder System described in this section has the same intended use and the same fundamental scientific technology as the cleared Arthrex Eclipse Shoulder Prosthesis System (K183194). Clinical evidence demonstrates that a high majority of patients saw a reduction in pain and increase in function as measured by the Adjusted Constant Score and is comparable to other anatomic total shoulder devices. The overall adverse event rate was low and the stemless humeral design did not create an increased risk for loosening or revision. The Easytech Anatomical Shoulder System has an equivalent safety profile and is at least as safe as other total anatomic shoulder arthroplasty systems in regards to all potential risks, including adverse event rates. The primary effectiveness and safety hypotheses both demonstrate clinical success equivalent to the primary predicate device.

Overall, the Easytech Anatomical Shoulder System has a positive risk-benefit profile. The study supports with high probability ($p < 0.0001$) that patients will experience a clinically significant improvement in pain and function, and has a similar safety profile compared to other legally marketed stemless anatomic shoulder devices.

Differences between the subject device and the predicate do not raise new questions of safety and effectiveness. Based upon the testing and clinical evidence, the Easytech Anatomical Shoulder System is substantially equivalent to the predicate device.