Ensemble Orthopedics, LLC
Sandie Roth
VP, Regulatory Affairs
107 Redbud Trail, Suite 11
Austin, Texas 78746

December 2, 2020

Re: K201072
Trade/Device Name: Ensemble CMC, Size 141, Ensemble CMC, Size 151, Ensemble CMC, Size 161
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist Joint Carpal Trapezium Polymer Prosthesis
Regulatory Class: Class II
Product Code: KYI
Dated: October 30, 2020
Received: November 2, 2020

Dear Sandie Roth:

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,

Vesa Vuniqi
Assistant Director
DHT6A2: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201072

Device Name
ENSEMBLE CMC

Indications for Use *(Describe)*
The Ensemble CMC is intended to replace the joint between the first metacarpal and the trapezium in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis, or post fracture deformation of bone loss which present as either a painful, unstable thumb, or a thumb with limited range of motion.

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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ENSEMBLE
ORTHOPEDICS LLC

510(k) Summary
Ensemble CMC

July 24, 2020

Submitter:
Ensemble Orthopedics, LLC
107 Redbud Trail, Suite 11
Austin, TX 78746
Tel: (512) 364-3830
Contact: Sandie Roth, VP of Regulatory
Email: sroth@ensembleortho.com

Establishment Registration Number: TBD

Name and Classification:

Trade Name:	ENSEMBLE CMC
Common Name:	Carpometacarpal implant
Regulation Name:	Wrist joint carpal trapezium polymer prosthesis
Classification:	21 CFR 888.3770
Product Code:	KYI
Regulatory Class:	Class II

Predicate Devices:

K042690	Ascension PyroSphere, Cleared December 13, 2004
K061451	Ascension CMC, Cleared August 11, 2006
K092548	Extremity Medical Trapezium, December 15, 2009
K111068	Stablyx CMC Arthroplasty, Cleared December 30, 2011
K033529	Tie-In Trapezium, Cleared December 3, 2003

Description of the Device:
The Ensemble CMC implant is a single use, uncemented, one-piece interpositional joint prosthesis designed to fit in the space between the trapezium and first metacarpal for patients with early stage arthritis of the carpometacarpal joint (CMC). The Ensemble CMC is not intended to interact with other devices. It has upper and lower surfaces that are saddle (toroidal) shaped to match the anatomy of the base of the first metacarpal and the trapezium. The design of the Ensemble CMC allows for flexion-extension, abduction-adduction, and circumduction motions. The implant is manufactured with an

On-X® PyroCarbon (pyrocarbon) layer encasing a graphite core and comes in three sizes. Each device is provided sterile in packaging containing a single implant, Instructions for Use, and patient chart labels.
A series of non-powered, hand-held manual surgical instruments can be used to prepare the joint space before implantation of the Ensemble CMC.

Intended Use:
The Ensemble CMC is intended to replace the joint between the first metacarpal and the trapezium in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis, or post fracture deformation of bone loss which present as either a painful, unstable thumb, or a thumb with limited range of motion.

Technological Characteristics:
The substantial equivalence of the Ensemble CMC to the predicate device is demonstrated by similarities in indications for use, device design, materials, manufacturing process, anatomical site, principles of operation, and sterility status. A comparison of technological characteristics of the Ensemble CMC and the predicate devices do not raise any new questions of safety or effectiveness.

Non-Clinical Testing:
Non-clinical mechanical testing was performed to demonstrate that the Ensemble CMC is substantially equivalent to the performance characteristics of the predicate devices currently marketed with respect to material characteristics, joint biomechanics, static and endurance testing. Cadaveric testing was performed to demonstrate the allowable range of motion and to confirm that the device does not cause impingement. Based on the results of the non-clinical testing, it can be concluded that the subject device is as safe and effective as legally marketed predicate devices.

Clinical Performance:
No clinical performance data were needed to support substantial equivalence of this implant to the predicate device.

Conclusion:
The Ensemble CMC is substantially equivalent to the predicate device identified in this premarket submission.