July 10, 2025

Keri Medical SA
℅ Camille Miletto
Regulatory Affairs Manager
Keri Medical
5 chemin du pré-fleuri
Plan-les-Ouates, CH-1228
Switzerland

Re: P240020
Trade/Device Name: TOUCH® CMC 1 Prosthesis
Product Code: SFA
Filed: June 7, 2024
Amended: April 11, 2025

Dear Camille Miletto:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the TOUCH® CMC 1 Prosthesis. This device is indicated for 1st carpometacarpal (CMC) primary total joint replacement (arthroplasty) in patients with symptomatic Eaton-Littler stage II or III osteoarthritis (OA). Based upon the information submitted, the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to all other applicable requirements, including those governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 5 years.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should

be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and must include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, under 21 CFR 814.82(a)(9), the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

You must obtain approval of your post-approval study (PAS) protocol(s) within 60 days from the date of this order. Within 30 days of your receipt of this letter, you must submit PMA supplements that include complete protocols of your post-approval studies described below. Your PMA supplements should be clearly labeled as a "PMA Post-Approval Study Protocol" as noted below and submitted to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below.

1. **Continued Long-Term Follow-up Study:** You have agreed to a study outline sent via email dated June 4, 2025. This will be a continued follow-up of the outside of the United States (OUS) patients enrolled in the prospective, single-center, single-arm PMA TOUCH® study to evaluate the long-term safety and effectiveness of the TOUCH® CMC 1 Prosthesis. All 103 remaining patients at time of PMA approval, from the original 149 patients, will be followed out to 5 years post-implantation for clinical and radiographic evaluation. You have agreed to take reasonable measures to avoid loss to follow-up and statistically analyze impact of any missing data.

    a. The primary endpoint will assess device composite clinical success (CCS) at 5 years post-implantation. To be considered as a success, a patient must meet all of the following criteria:
        i. Improvement of pain: a clinically meaningful improvement in pain defined as a decrease in the pain sore of ≥ 30% on a 10-point scale.
        ii. Maintenance or improvement in function: defined by key pinch strength, which is ≥ 85% of the subject's pre-operative key pinch strength.
        iii. Safety: success is defined as freedom from:
            1. Subsequent surgical interventions (SSI) (i.e., reoperation, revision, removal of any study component, or supplemental fixations) on the study carpometacarpal joint, or
            2. Serious, device- or procedure-related adverse events.

    b. Secondary Endpoints will assess:
        i. Pain evolution (% change) at rest and during activities, as measured by Numerical Rating Scale (NRS) on a 10-point scale
        ii. Key pinch strength (kg) evolution
        iii. Kapandji Index
        iv. Patient satisfaction via brief Michigan Hand Outcomes Questionnaire (bMHQ)
        v. Return to work time

vi. Radiographic success when determined medically necessary by the investigator: absence of device migration, osteolysis, radiolucencies or fracture
vii. Individual components of the CCS including need for revision surgery and serious, device-related adverse events

c. Exploratory Endpoints include:
   i. QuickDASH

In order to supplement data missing from individual components of the CCS endpoint, you have agreed to provide additional analyses of 5-year patient-level outcome data from both a retrospective post-market clinical follow-up study conducted by Keri Medical, and a prospective study published by Falaise et al. in 2025.

PAS Progress Reports must be submitted every six (6) months for the first year and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA. The Final PAS Report should be submitted no later than three (3) months after study completion (i.e., last subject's last follow-up date).

2. **TOUCH® CMC 1 New Enrollment US Study**: You have agreed to a study outline sent via email dated June 4, 2025, to evaluate the device performance in United States (US) patients implanted by US surgeons when compared to device performance observed within the outside the US (OUS) premarket cohort. This will be a prospective, multicenter, single-arm study with hypothesis testing to evaluate device performance among newly enrolled patients treated with TOUCH® CMC 1 Prosthesis in the US for primary total replacement of the first carpometacarpal joint in patients with Eaton-Littler stage II or III osteoarthritis. Study subjects will undergo clinical and radiographic evaluation for the following primary and secondary endpoints assessed for at least through 2 years post-implantation (i.e., at 6 weeks, 3 months, 1 year, and 2 years, with initial patient informed consent for 5 years of follow-up for assessment after 2 years if needed).

   a. The primary endpoint will assess device CCS at 2 years post-implantation. To be considered as a success, a patient must meet all of the following criteria:
      i. Improvement of pain: a clinically meaningful improvement in pain defined as a decrease in the pain sore of ≥ 30% on a 10-point scale.
      ii. Maintenance or improvement in function: defined by key pinch strength, which is ≥ 85% of the subject's pre-operative key pinch strength.
      iii. Safety: success is defined as freedom from:
         1. Subsequent surgical interventions (SSI) (i.e., reoperation, revision, removal of any study component, or supplemental fixations) on the study carpometacarpal joint, or
         2. Serious, device- or procedure-related adverse events.

      For hypothesis testing on the primary endpoint, the performance goal will be based on the performance (CCS) of the premarket cohort at 2 years. A minimum of 163 US subjects will be enrolled across a minimum of 4 US sites ensuring that no single site enrolls greater than 25% of subjects. The sample size is based on the following assumptions: 80% power, one-sided Type I error of 2.5%, performance goal of 73.8% and a lost to follow-up rate of 15% at 2 years.

b. Secondary endpoints to be assessed are (1) pain at rest; (2) pain during activities; (3) key pinch strength (kg); (4) Kapandji Index; (5) bMHQ; (6) range of motion (thumb metacarpal flexion, thumb metacarpal radial abduction, thumb metacarpal palmar abduction, thumb length); (7) PROMIS (Patient-Reported Outcomes Measurement Information System) upper extremity computer adaptive test (CAT); (8) PROMIS pain interference CAT; (9) EQ-5D-5L; (10) EQ-5D-VAS); (11) return to work (days) in those working at baseline; (12) patient satisfaction (including aesthetic); (13) radiographic endpoints (device migration, osteolysis, radiolucencies, fracture); and (14) individual components of the safety endpoint (including SSIs and adverse events).

   For hypothesis testing on the secondary endpoints, you have agreed to compare the success of each component of the CCS endpoint to the performance of the premarket cohort with a reference margin of 10% at 2 years.

From the time of study protocol approval, you must meet the following timelines for the **TOUCH® CMC 1 New Enrollment US Study** PAS:

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months
- 100% of subjects enrolled within 24 months

In addition, you must submit separate periodic reports on the progress of the **TOUCH® CMC 1 New Enrollment US Study** PAS as follows:

- PAS Progress Reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA.
- If any enrollment milestones are not met, they must begin submitting quarterly enrollment status reports every 3 months in addition to their periodic (6-month) PAS Progress Reports, until FDA notifies otherwise.
- Submit the Final PAS Report three (3) months from study completion (i.e., last subject's last follow-up date).

Information regarding interim study progress and results (including number of study sites and patients enrolled, and a summary of key study endpoints for both post-approval studies will be posted on the FDA's Post-Approval Studies (PAS) Program Database webpage (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm) after submission of each interim report.

Each PAS report should be submitted to the address below identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement, including initiation, enrollment, and completion of the requirements above, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post-Approval Studies Program Database Webpage, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

In addition, the results from any post approval study should be included in the labeling as these data become available. Under 21 CFR 814.39, any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order" (https://www.fda.gov/media/71327/download).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. Additional information about changes that may require a PMA supplement are provided in the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" https://www.fda.gov/media/81431/download.

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production and process controls (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR Part 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical

devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product post-marketing safety reporting is available at https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products.

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR Part 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Joseph Russell at 240-402-4210 or Joseph.Russell@fda.hhs.gov.

Sincerely,

JIPING CHEN -S

Jiping Chen, M.D., Ph.D., M.P.H.
Director
DHT6A: Division of Joint Arthroplasty Devices
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Office of Product Evaluation and Quality
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