SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Prosthesis, finger, semi-constrained, metal/polymer
Device Trade Name:	TOUCH® CMC 1 Prosthesis
Device Procode:	SFA
Applicant's Name and Address:	Keri Medical SA Chemin du Pré-Fleuri 5, 1228 Plan-les-Ouates, Switzerland
Date(s) of Panel Recommendation:	None

Premarket Approval Application (PMA) Number: P240020

Date of FDA Notice of Approval: July 10, 2025

Breakthrough Device: Granted breakthrough device status on November 10, 2021, because the device and proposed indication for use met criteria.

II. INDICATIONS FOR USE

TOUCH® CMC 1 Prosthesis is intended for 1st carpometacarpal (CMC) primary total joint replacement (arthroplasty) in patients with symptomatic Eaton-Littler stage II or III osteoarthritis (OA).

III. CONTRAINDICATIONS

- Acute or chronic infections, local or systemic.
- Muscular, neurological, or vascular severe deficiency affecting the joint.
- Inadequate bone quality or quantity preventing implant fixation.*
- Bones dimensions incompatible with implant sizes.
- Patients who are allergic to the product's materials.
- Any concomitant disorder that may affect the function of the implant.

*Note: (as evaluated by x-ray radiography or x-ray computed tomography (CT) based on physician judgment).

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the TOUCH® CMC 1 Prosthesis labeling.

V. DEVICE DESCRIPTION

The TOUCH® CMC 1 Prosthesis is a cementless, ball-and-socket dual-mobility total carpometacarpal (CMC) prosthesis (thumb base joint replacement) implant which is made up of three modular components available in a variety of sizes to accommodate varying patient anatomy:

- TOUCH® Cup: a stainless steel trapezial implant (cup) with a dual coating of plasma sprayed titanium and hydroxyapatite; TOUCH® Cup is available in two options: Spherical and Conical.
- TOUCH® Neck and Liner: a junction implant (neck) topped with a highly cross-linked ultra-high molecular weight polyethylene (UHMWPE) liner pre-assembled to stainless steel neck.
- TOUCH® Stem: a titanium alloy metacarpal implant (stem) with a dual coating of plasma sprayed titanium and hydroxyapatite.

TOUCH® CMC 1 Prosthesis is intended to surgically treat symptomatic 1st carpometacarpal (CMC) joint osteoarthritis (OA) by total joint replacement (arthroplasty). All implants are packaged sterile via gamma irradiation with a 5-year shelf life. **Figure 1** shows the components alone and as implanted in the final location

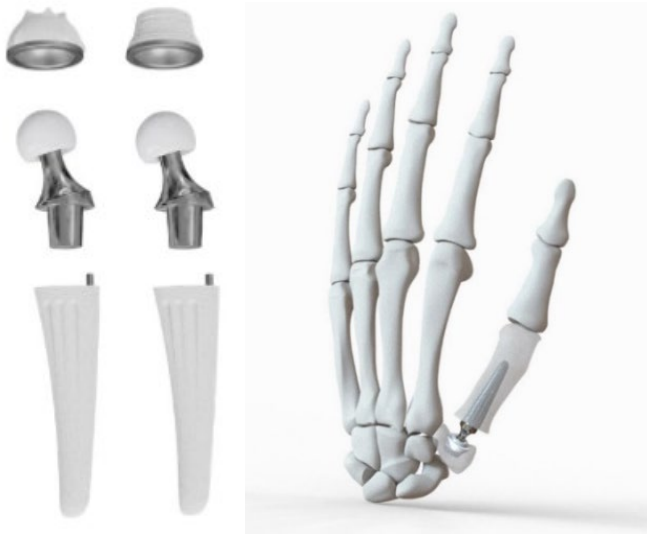


Figure 1. TOUCH® CMC 1 Prothesis (left) and Visualization of the Device Implanted in the first CMC (right).

The TOUCH® CMC 1 Prosthesis is implanted using dedicated, reusable instrumentation in a bone-preserving surgical procedure. The TOUCH® instrumentation includes a

complete set of implant patterns, handles, cannulated trapezium starters, reamers, forceps, retractors, impactors, holders, and rasps. A dedicated instrument tray, with racks and lids, is also provided. All instrumentation is non-sterile and reusable with cleaning and sterilization instructions provided in the labeling. Please refer to the labeling for additional details.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative treatments for symptomatic Eaton-Littler stage II or III thumb osteoarthritis include:

- Thermotherapy
- Exercise therapy
- Electrotherapy
- Orthoses
- Topical treatments
- Non-steroidal anti-inflammatory drugs (NSAIDs) and highly selective cyclooxygenase-2 (COX-2) inhibitors
- Intra-articular injections
- Ligament reconstruction
- Osteotomy
- Trapeziectomy alone
- Trapeziectomy with hematoma distraction
- Trapeziectomy with tendon interposition
- Trapeziectomy with or without suspension arthroplasty (LRSA/LR)
- Trapeziectomy with interposition arthroplasty
- Trapeziectomy with ligament reconstruction and tendon interposition (LRTI)
- Interposition implants
- Hemiarthroplasty
- Arthrodesis

Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method(s) that best meets their expectations and lifestyle.

VII. MARKETING HISTORY

The TOUCH® CMC 1 Prosthesis has been commercially distributed by Keri Medical based on the device's CE Mark since 2018. In addition to the European Union (EU), the device has been marketed in South Africa, Singapore, Israel, Qatar, United Arab Emirates, Argentina, Chile, and New Zealand. The TOUCH® CMC 1 Prosthesis has not been withdrawn from distribution/marketing in any country for safety or effectiveness reasons.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The potential adverse effects associated with the use of the TOUCH® CMC 1 Prosthesis may be related to the device or the procedure, and are typical risks associated with orthopedic devices and total joint arthroplasty surgery. Below is a list of the potential adverse effects:

- Wear
- Mechanical failure (component breakage or deformation, corrosion, impingement, disassembly)
- Adverse tissue reaction
- Bone fracture during implantation
- Osteolysis around the implant
- Implant migration/ loosening/ sub-optimal osseointegration
- Infection
- Dislocation/ subluxation
- Painful and/or limited range of motion
- Radiographic failure

In addition to the adverse effects listed above, there is always the risk that surgery may not be effective in relieving symptoms or may cause worsening of symptoms. Additional surgery may be required to correct some of the adverse effects (events).

For the specific adverse events that occurred in the clinical study, please see Section X below.

IX. SUMMARY OF NON-CLINICAL STUDIES

A. Laboratory Studies

Table 1. Laboratory Studies Overview

Figure	Purpose	Acceptance Criteria	Results
Wear Testing (Mode I)	To evaluate the wear performance of devices under pristine conditions.	No mechanical failure of the components, wear rates and particulate debris of no concerning rate or morphology, and no decreased resistance to disassembly of the modular head from the neck due to impingement.	All devices under pristine loading survived the pre-specified number of cycles with acceptable wear rates, particle morphology and no device failure. With increasing load and cycle count, samples failed by liner wear through after additional cycles at an

Figure	Purpose	Acceptance Criteria	Results
			increased load magnitude.
Wear Testing (Mode III)	To evaluate the wear performance of devices under abrasive conditions.	No mechanical failure of the components.	All but one device under abrasive loading survived the predetermined number of cycles of wear under abrasive conditions. The one failure by liner wear through was deemed acceptable due to the worst-case abrasive conditions exceeding expected clinical conditions. With increasing load and cycle count, samples failed by liner wear through after additional cycles at an increased load magnitude.
Wear Testing (Mode IV)	To evaluate whether impingement of the neck/liner assembly on the cup adversely impacted component disassembly resistance.	No decreased pull-off strength of the liner from the neck due to impingement.	All devices survived the predetermined number of cycles of impingement. Impingement did not adversely impact the disassembly resistance of the liner from the neck.
Fatigue Testing	To evaluate the fatigue performance of devices to validate sufficient device strength for its intended use.	No device failure characterized by liner breakage/perforation or plastic deformation greater than a prespecified displacement through the predetermined cycle count.	All devices survived the predetermined cycle count of fatigue loading. One sample exhibited permanent yield of the liner after exposure to increased cyclic loading at an increased load magnitude.
Fretting and Corrosion Testing at the	To characterize fretting corrosion resistance of the stem-	No device failure during loading with minimal corrosion	All devices survived the predetermined cycle count. Post-

Figure	Purpose	Acceptance Criteria	Results
Stem-Neck Junction	neck junction of devices.	observed on the modular taper junction.	disassembly evaluation of the taper surfaces exhibited only mild evidence of corrosion on the Goldberg Scale. (Goldberg et. al. 2002)
Stem/Neck Disassembly	To evaluate the disassembly resistance of the device.	Device's disassembly resistance should be greater than anticipated disassembly loads for the device design for its intended use.	All devices withstood expected disassembly forces expected for the device design based on its intended use.
Neck/Liner Disassembly	To evaluate the disassembly resistance of the device.	Device's disassembly resistance should be greater than anticipated disassembly loads for the device design for its intended use.	All devices withstood expected disassembly forces expected for the device design based on its intended use.
Range of Motion	To provide objective evidence that implantation of the device in cadaveric specimen did not adversely impact range of motion of the first carpometacarpal.	Range of motion of the joint after implantation of the device should be equivalent or greater than the range of motion of the native joint.	Maximal abduction-adduction and flexion-extension of the joint were equivalent or greater after implantation of the device when compared to the native anatomy.

B. Additional Studies

Table 2. Additional Testing Overview

Test	Purpose	Test Method	Results
Biocompatibility	Demonstrate that the TOUCH® CMC 1 Prosthesis is biocompatible	ISO 10993-1	All patient contacting materials are biocompatible.
Sterilization	Sterilization validation ensures the sterilization process is adequate.	ISO 11137-1 and – 2	Sterility Assurance Level of 10^{-6} was achieved.
Stability	Shelf-life determination	ANSI/AAMI/ISO 11607	A shelf-life period of 5 years was substantiated.

Test	Purpose	Test Method	Results
Cleaning/Sterility of Reusable Components	Steam sterilization validation and cleaning validation	ISO 17665 ISO 19227	Sterility Assurance Level of 10^{-6} was achieved. Cleaning methods sufficiently reduced soil on reusable instrumentation.

Magnetic Resonance (MR) Imaging

The safety and compatibility of the TOUCH® CMC 1 Prosthesis in the MR environment was evaluated. Specifically, it was tested for magnetic field interactions, heating, and artifacts associated with clinically relevant magnetic resonance testing. The effects of displacement force and torque effects were performance in accordance with ASTM F2052 and ASTM F2213. The effects of radiofrequency induced heating were tested in accordance with ASTM F2182. MR imaging artifacts were assessed in accordance with ASTM F2119.

The results of the assessments demonstrated that the TOUCH® CMC 1 Prosthesis is MR conditional. A patient implanted with the TOUCH® CMC 1 Prosthesis may be safely scanned at 1.5 T or 3 T under the following conditions:

MRI Safety Information

A person with KeriMedical's TOUCH Implant may be safely scanned at 1.5 T or 3 T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	KeriMedical's TOUCH Implant
Static Magnetic Field Strength (B0)	1.5 T and 3 T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	30 T/m (3,000 G/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
Whole Body Averaged SAR	Whole Body Averaged SAR ≤ 2 W/kg
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks).
Image Artifact	The presence of KeriMedical's TOUCH Implant may produce an image artifact of 5.3 cm. Some manipulation of scan parameters may be needed to compensate for the artifact.
Patient Characteristics	The safety of this item during scanning has not been proven if there is another implant within 2 cm.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study titled: "Comparison between TOUCH® CMC 1 Prosthesis and Trapeziectomy with LRTI: prospective observational cohorts," (referred to as the "TOUCH®" study) to establish a reasonable assurance of safety and effectiveness of primary first carpometacarpal total joint arthroplasty with the TOUCH® CMC 1 Prosthesis for Eaton-Littler stage II or III osteoarthritis in Switzerland. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

The primary objective of the study is to evaluate the safety and effectiveness of the TOUCH® CMC 1 Prosthesis, compared to the control treatment, trapeziectomy with ligament reconstruction and tendon interposition (LRTI).

Patients in the control group were treated between March 2014 and January 2017 while patients in the investigational group (referred to as TOUCH® subjects), were treated between June 2018 and January 2022. The database for this PMA reflected data collected through March 1, 2024, and included 276 patients. After applying inclusion/exclusion criteria and subject trimming during propensity score (PS) modeling, 225 patients were included in the final study.

The study was a retrospective clinical study. There was one investigational site with nine different surgeons of varied experience. Data were prospectively collected in the hand surgery department of a tertiary orthopedic hospital in Switzerland (Schulthess Klinik, Zurich). The study compared the outcomes of prospectively collected single center data from 149 subjects undergoing thumb CMC joint arthroplasty with the investigational device when compared to a PS adjusted historical control cohort of 76 subjects undergoing CMC joint trapeziectomy, LRTI.

The primary safety and effectiveness endpoint is Composite Clinical Success (CCS) evaluated at 24 months for the TOUCH® group and 12 months for the control LRTI group. The components of the CCS were comprised of three outcomes (pain, function, and safety). The individual components of the primary outcome measures were the Numerical Rating Scale (NRS) score for pain during activities, maintenance or improvement in function defined/ measured via key pinch strength, and safety success (defined as freedom from serious device-related (TOUCH®) or serious procedure-related (LRTI) adverse events, or subsequent surgical interventions (SSI)). The CCS defined subject level success in which all criteria must be met for a subject to be considered a success.

Comparison of the 24-month endpoint for the investigational device to a 12-month endpoint for the control was justified through a systematic literature review including 16 published articles reporting on 512 subjects who underwent the control procedure. All studies reported results at 12 months and/or 24 months following surgical

intervention. Conclusions drawn from the literature review report that patients undergoing the control procedure:

- Experienced a reduction in pain from baseline to 12 months, followed by a slight increase in pain between 12 and 24 months;
- Experienced an improvement in function from baseline to 12 months, followed by a decline in function between 12 and 24 months as evidenced by Key Pinch Strength, Kapandji Index, and DASH scores;
- Experienced reduced symptoms and improvement in ability to perform functions between baseline and 12 months followed by an increase in symptoms and a decrease in ability to perform functions between 12 months and 24 months as evidenced by the DASH scores; AND
- Experienced a higher cumulative failure rate at 24 months compared to 12 months.

The literature provided suggests that outcomes of LRTI are comparable at both timepoints or effectiveness outcomes may be slightly better at 12 months than at 24 months.

This was a non-inferiority study with an a priori selected non-inferiority margin (δ) of 15%. The primary effectiveness hypothesis is non-inferiority of the investigational device relative to control for CCS success comparing subject-level CCS success proportion between the investigational and control subjects. The null (Ho) and alternative (Ha) hypotheses can be symbolically represented as:

Ho: πTOUCH® - πLRTI $\leq -\delta$
Versus
Ha: πTOUCH® - πLRTI $> -\delta$

Where πTOUCH® is the proportion of successful TOUCH® subjects and πLRTI is the proportion of successful control subjects.

In addition to the outcomes comprising the primary composite endpoint, other functional outcomes were studied and included NRS change scores at rest, NRS change scores during activity, key pinch and change scores, thumb opposition using the Kapandji Index, brief Michigan Hand Outcomes Questionnaire (bMHQ) scores, Quality of Life (EQ-5D-5L) scores, EQ-5D-VAS scores, time to return to work, and individual components of the CCS including need for revision surgery. Radiographic evaluation of the TOUCH® CMC 1 Prosthesis was conducted by an independent core reading facility according to the Schulthess Klinik protocol.

Propensity score (PS) designs were evaluated to account for potential selection bias in the non-randomized comparison between the investigational group (TOUCH® CMC 1), and the historical control group (LRTI). To identify the optimal PS-designed comparison between TOUCH® CMC 1 and LRTI groups, two approaches were evaluated – subclassification using PS quintiles and PS weighting. Keri Medical's outcomes-blinded PS design statistician selected the PS-weighted design, based on

the evaluation of balance achieved in individual baseline covariates and other design-specific characteristics (**Table 3** and **Figure 2**).

The PS weighted design utilized weights that resulted in an average treatment effect among the treated (ATT). The PS weighted approach improved balance in nearly all included covariates while retaining all 149 eligible TOUCH CMC® 1 patients and trimming only 4 (5.0%) of 80 eligible LRTI controls with PS values outside of the 10% region of support. The optimal PS model for generating PS weights was determined to be the model including all main effects plus two additional higher-ordered terms ([Kapandji Index] x [EQ-5D Utility] and [Age at surgery] x [Brief MHQ Score]). After applying the PS weights in the final model, all but one covariate had a |Standardized Mean Difference (SMD)| < 0.20; employment status had a slightly elevated SMD of 0.307. The PS weighted approach was able to partially overcome the sub-optimal characteristics of the PS subclassification approach, particularly the challenges that arise from low sample sizes within individual quintiles.

Baseline differences in the study groups were evaluated by a blinded PS design and informed the comparison of the two groups of this study. FDA noted that use of the PS-weighted approach limited the comparability of the study populations and contributed to the uncertainty regarding the results of the primary evaluation. Therefore, the non-inferiority hypothesis testing for the primary endpoint (CCS) may be biased and uninterpretable from a statistical perspective. As such, the primary endpoint evaluation is presented using descriptive statistics only.

Table 3. Comparison of TOUCH® Study Baseline Covariate Balance between TOUCH® CMC 1 and LRTI participants in the Final PS Weighted Design data set.

Measure	Touch CMC 1®	LRTI	p†	SMD‡
N	149	134.3*	–	–
Age at Surgery	62.7 ± 8.1	62.8 ± 11.7	0.918	-0.012
Kapandji Index	8.74 ± 1.91	8.64 ± 2.43	0.714	0.044
Brief MHQ Score	44.5 ± 14.1	41.9 ± 18.7	0.194	0.156
Pain at rest (NRS)	5.22 ± 2.40	5.35 ± 2.57	0.663	-0.051
Pain during activities (NRS)	7.44 ± 1.71	7.46 ± 1.91	0.932	-0.010
EQ-5D-5L Utility Index	0.73 ± 0.17	0.74 ± 0.27	0.801	-0.030
EQ-5D Visual Analog Scale	73.7 ± 18.5	72.7 ± 25.3	0.709	0.045
Key Pinch in Affected Hand	4.59 ± 2.60	4.59 ± 2.93	0.985	-0.002
Male Gender	28.2%	35.9%	0.164	-0.166
Dominant Side (Right)	79.9%	75.7%	0.404	0.099
Affected Side (Right)	48.3%	44.1%	0.478	0.085
Eaton Stage II of Osteoarthritis	16.1%	23.3%	0.130	-0.180
Employed	57.0%	41.9%	0.011	0.307

†Two-sided p-values from t-tests for continuous variables and chi-squared tests for categorical variables, after PS-derived weighting; ‡Standardized mean difference; *represents the total sum of control weights among the 76 unique LRTI control participants

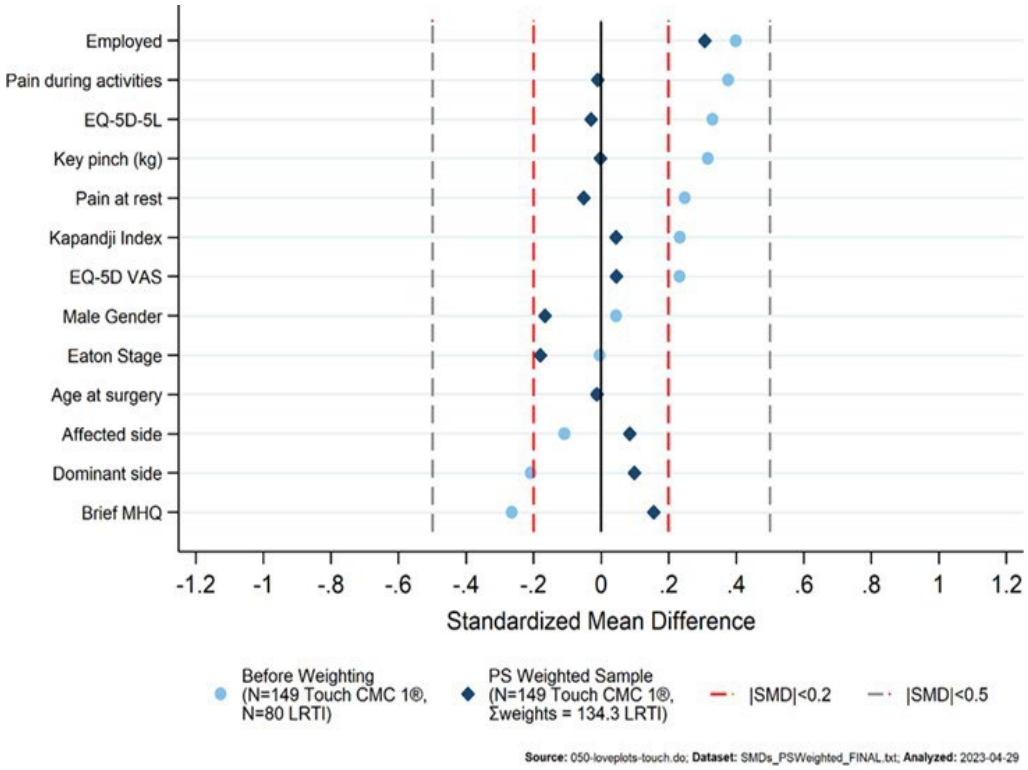


Figure 2. TOUCH® Study Love Plot illustrating improved balance in covariates achieved through final PS weighted design based on standardized mean differences.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the TOUCH® study was limited to patients who met all of the following inclusion criteria:

- Adult patient (>22 years)
- Surgically treated with thumb carpometacarpal joint arthroplasty (TOUCH® CMC 1 Prosthesis) or with trapeziectomy and LRTI after conservative treatment failure (splint, one to three steroid injections)
- Patients with Eaton II or III
- Patients with a Swiss or international health insurance or are being treated at their own expense

Note; all control subjects were included only if they could have been eligible to receive the investigational device

Patients were not permitted to enroll in the TOUCH® study if they met any of the following exclusion criteria:

- No consent for reuse of the data
- Pregnant women

- Patients who received the TOUCH® CMC 1 Prosthesis as a revision procedure
- Patients with contraindications to surgery in general
- Poor bone quality preventing implant fixation
- Any concomitant disorder that may affect the function of the implant (e.g., osteoarthritis of the wrist)

2. Follow-up Schedule

Following a baseline visit, treated patients were assessed post-operatively at follow-up visits. Post-procedure follow-up evaluated the patient's hand condition and clinical health. Follow-up visits were performed at 6 weeks, 3 months, 12 months, and 24 months. As mentioned above, patients receiving the control procedure were only followed to 12 months.

The key timepoints are shown below in the table summarizing safety and effectiveness assessment visits.

Table 4. TOUCH ® Study Activity Schedule

	Baseline	Surgery	6 weeks[1]	3 months	1 year	2 years[1]
Sociodemographic	X					
Diagnosis	X					
Eaton stage of OA	X					
Surgery detail		X				
Implant detail[1]		X				
Kapandji	X		X	X	X	X
Brief MHQ	X		X	X	X	X
Pain at rest	X		X	X	X	X
Pain during activities	X		X	X	X	X
EQ-5D-5L	X		X	X	X	X
EQ-5D VAS	X		X	X	X	X
Return to work			X	X	X	X
Key pinch	X		X	X	X	X
Radiography	X		X	X[1]	X[1]	X
Adverse event		X	X	X	X	X

[1] *Data only for the TOUCH® group. Control group patients returned only for 3-month and 1-year follow-up visits.*

3. Clinical Endpoints

The primary composite clinical success endpoint of the study was designed to measure both safety and effectiveness. To be determined as a success, a subject must meet all of the following criteria:

1. **Improvement in pain:** a clinically meaningful improvement in pain is defined as a decrease in the Numerical Rating Scale (NRS) pain score (during activities) of $\geq 30\%$ on a 10-point scale.

2. **Maintenance or improvement in function:** defined by key pinch strength which is ≥ 85% of the subject's pre-operative key pinch strength.
3. **Safety:** success is defined as freedom from:
    a. Subsequent surgical interventions (SSI) (i.e., reoperation, revision, removal, or modification of any study component, or supplemental fixations) on the study carpometacarpal joint, OR
    b. Serious device- or procedure-related adverse events.

Secondary effectiveness endpoints included pain (NRS) at rest, pain (NRS) during activities, key pinch via a pinch gauge, thumb opposition via the Kapandji Index, hand function via bMHQ, quality of life via EQ-5D-5L, overall health via EQ-5D-VAS, time to return to work, individual components of the primary endpoint, and radiographic evaluation (TOUCH group only) for the presence of cup migration, radiolucent lines, or fracture.

With regards to safety, all adverse events were reviewed and uniformly evaluated categorized by severity, as well as whether the events were device or procedure related along with the relationship of the event (i.e., definitely, probably, possibly, or not related).

B. Accountability of PMA Cohort

Of the 150 TOUCH® subjects, one subject was excluded for Eaton stage I osteoarthritis. Of the 126 control LRTI subjects, 46 subjects were excluded for Eaton stage IV osteoarthritis, and 4 subjects were trimmed during the PS design. The primary analysis population includes 149 subjects treated with TOUCH® and 76 subjects treated with LRTI (**Figure 3** and **Table 5**).

Of the 225 patients included in the primary analysis dataset, 92.8% (209) patients were available for analysis at the completion of the study, i.e., the 2-year post-operative visit for the TOUCH® device or the 1-year post-operative visit for the control LRTI.

The subject accountability and clinical follow-up compliance is presented in **Table 5** for the final analysis population. The follow-up compliance rate for CCS is 77.7% for the TOUCH® group at 24 months and 65.8% for the control group at 12 months.

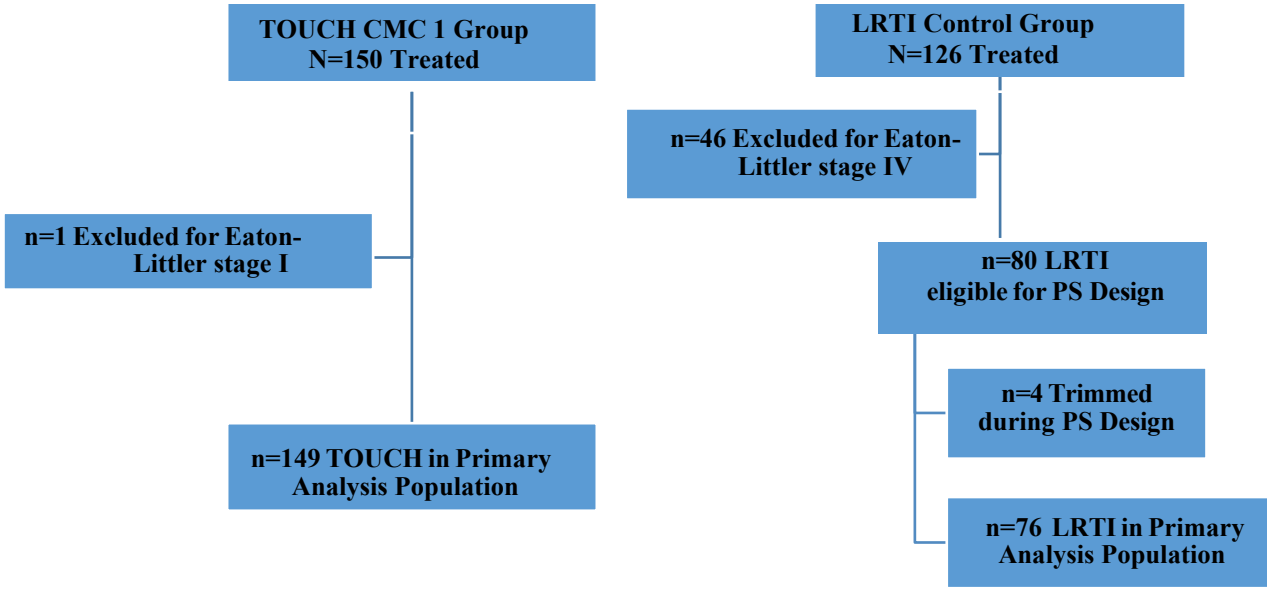


Figure 3: Subject Accounting Trees for the TOUCH® Study Investigative and LRTI Control Groups.

Table 5: TOUCH® Study Subject Accounting and Clinical Follow-up Compliance Table for the PS Selected Modified Intent to Treat (mITT) Analysis Set[2]

Date of data lock 20240301	Baseline		Week 6		Month 3		Month 12		Month 24		Final[2]	
	I	C	I	C[3]	I	C	I	C	I	C[3]	I	C
[1] Theoretical Due	149	76	149		149	76	149	76	149		149	76
[2] Deaths (cumulative)*	---	---	0		0	0	0	0	1		1	0
[3] Secondary Surgical Intervention (cumulative)*	---	---	1		1	0	3	1	9		9	1
[4] Expected = [1] - [2] - [3]	149	76	148		148	76	146	75	139		139	75
[5] Any Clinical Data	149	76	146		144	76	146	75	133		133	75
[6] % Follow-up = [5] / [4]	100.0%	100%	98.6%		97.3%	100%	100.0%	100%	95.7%		95.7%	100%
[7] Pain (During Activities) Responder[1]	142	76	130		131	76	134	75	122		122	75
[8] % Follow-up for Pain (During Activities) = [7]/[4]	95.3%	100%	87.8%		88.5%	100%	91.8%	100%	87.8%		87.8%	100%
[9] Key Pinch Strength Responder[1]	147	75	135		110	61	132	49	117		117	49
[10] % Follow-up for Key Pinch Responder[1] = [9]/[4]	98.7%	98.7%	91.2%		74.3%	80.3%	90.4%	65.3%	84.2%		84.2%	65.3%
[11] CCS							---	50	115		115	50
[12] % Follow-up for CCS = [13] / ([3] + [4])							---	65.8%	77.7%		77.7%	65.8%

Notes:

[1] Number with baseline and follow-up to determine responder status except for baseline. At baseline the number evaluated at baseline is reported.

[2] Month 24 for TOUCH and Month 12 for LRTI.

[3] The control group did not have a 6 week or Month 24 follow-up visits.

* Among theoretical due

** % Follow-up = any clinical/ (expected – not yet past due)

[2] *"I" stands for the investigational TOUCH® group and "C" stands for the control LRTI group.*

C. Study Population Demographics and Baseline Parameters

Table 6 and **Table 7** display a summary of the demographic continuous and categorical variables for all subjects in the investigational TOUCH® (N=149) and control LRTI (N=76) groups. The mean age at time of surgery was similar for both groups: 62.7 years for TOUCH® subjects and 63.4 years for the control. Both males and females were treated, with a higher percentage of females (about 70% females) in

both groups. Baseline Patient-Reported Outcome Measures (PROMs) data were also similar between groups.

Table 6: Summary of Demographic and Baseline Continuous Variables PS Selected mITT Analysis Set (N=149 TOUCH®, N=76 Control LRTI)

Date of data transfer 20240301	Touch						LRTI						Touch - LRTI[1]		
Demographics - All	**N**	**Mean**	**SD**	**Med**	**Min**	**Max**	**N**	**Mean**	**SD**	**Med**	**Min**	**Max**	**Diff**	**LB**	**UB**
Age at Surgery (yrs)	149	62.7	8.1	62.2	45.5	84.9	76	63.4	7.9	62.4	45.0	78.5	-0.71	-2.94	1.53
Demographics - Male	**N**	**Mean**	**SD**	**Med**	**Min**	**Max**	**N**	**Mean**	**SD**	**Med**	**Min**	**Max**	**Diff**	**LB**	**UB**
Age at Surgery (yrs)	42	64.2	7.5	63.2	52.3	80.4	20	65.0	7.8	66.1	45.0	78.5	-0.76	-4.88	3.36
Demographic - Female	**N**	**Mean**	**SD**	**Med**	**Min**	**Max**	**N**	**Mean**	**SD**	**Med**	**Min**	**Max**	**Diff**	**LB**	**UB**
Age at Surgery (yrs)	107	62.0	8.3	61.5	45.5	84.9	56	62.8	8.0	61.4	47.9	78.2	-0.74	-3.40	1.92
PROMs	**N**	**Mean**	**SD**	**Med**	**Min**	**Max**	**N**	**Mean**	**SD**	**Med**	**Min**	**Max**	**Diff**	**LB**	**UB**
Kapandji Index	145	8.73	1.93	10.00	0.0	10.0	75	8.33	1.86	9.00	2.0	10.0	0.40	-0.14	0.93
Brief MHQ	142	44.29	14.44	43.75	6.3	83.3	76	48.23	16.84	47.92	14.6	85.4	-3.93	-8.22	0.36
Pain at Rest	142	5.21	2.45	5.00	0.0	10.0	76	4.72	2.21	5.00	0.0	10.0	0.49	-0.18	1.15
Pain during Activities	142	7.43	1.75	8.00	3.0	10.0	76	6.88	1.74	7.00	1.0	10.0	0.55	0.06	1.04
EQ-5D-5L	141	0.73	0.17	0.79	0.2	1.0	76	0.67	0.22	0.74	0.0	1.0	0.06	0.01	0.12
EQ-5D VAS	138	73.54	19.17	80.00	8.0	100.0	76	69.88	19.75	71.00	10.0	99.0	3.66	-1.79	9.12
Key pinch (kg)	147	4.58	2.61	4.00	0.5	12.0	75	3.92	2.02	3.40	0.3	8.7	0.65	-0.02	1.33

Notes:

[1] Group differences and 95% confidence intervals (CI) for group differences.

[Source: Tables_BaselineDemo_cont.sas, Tables_BaselineDemo_cont_ci.sas]

Table 7: Summary of TOUCH® Study Baseline Categorical Variables – PS Selected mITT Analysis Set (N=149 TOUCH®, N=76 Control LRTI)

Date of data lock 20240301	Touch		LRTI		Touch - LRTI[1]		
	n	%	n	%	Diff (%)	LB	UB
Number of subjects	149		76				
Males	42	28.2	20	26.3	1.9	-10.4	14.1
Females	107	71.8	56	73.7			
Affected Side	**n**	**%**	**n**	**%**			
Right	72	48.3	42	55.3	-6.9	-20.7	6.8
Left	77	51.7	34	44.7			
Dominant side	**n**	**%**	**n**	**%**	**p[2]**		
Right (or not available)	119	79.9	66	86.8	0.195		
Left/Both	30	20.1	10	13.2			
Dominant side affected	**n**	**%**	**n**	**%**			
Yes	85	59.4	41	53.9	5.5	-8.3	19.3
No	58	40.6	35	46.1			
(not available)	6	0.0	0	0.0			
Other Hand in Registry	**n**	**%**	**n**	**%**			
Yes	32	21.5	0	0.0	21.5	14.9	28.1
No	117	78.5	76	100.0			
Employed	**n**	**%**	**n**	**%**			
Yes	81	56.6	28	36.8	19.8	6.3	33.4
No	62	43.4	48	63.2			
(not available)	6	4.0	0	0.0			
Diagnosis	**n**	**%**	**n**	**%**	**p[2]**		
OA	149	100.0	76	100.0			
Posttraumatic	0	0.0	0	0.0			
RA	0	0.0	0	0.0			
Other	0	0.0	0	0.0			
Eaton Stage of OA	**n**	**%**	**n**	**%**	**p[2]**		
II	24	16.1	11	14.5	0.749		
III	125	83.9	65	85.5			
Kapandji Index	**n**	**%**	**n**	**%**	**p[2]**		
0	1	0.7	0	0.0	0.015		
1	1	0.7	0	0.0			
2	0	0.0	1	1.3			
3	2	1.4	0	0.0			
4	1	0.7	0	0.0			
5	8	5.5	2	2.7			
6	7	4.8	16	21.3			
7	6	4.1	6	8.0			
8	15	10.3	8	10.7			
9	29	20.0	9	12.0			
10	75	51.7	33	44.0			
Pain at Rest	**n**	**%**	**n**	**%**	**p[2]**		
0	6	4.2	3	3.9	0.313		
1	5	3.5	4	5.3			
2	14	9.9	7	9.2			
3	11	7.7	7	9.2			
4	14	9.9	11	14.5			
5	25	17.6	13	17.1			
6	12	8.5	15	19.7			
7	31	21.8	10	13.2			
8	15	10.6	4	5.3			
9	6	4.2	1	1.3			
10	3	2.1	1	1.3			
Pain During Activities	**n**	**%**	**n**	**%**	**p[2]**		
0	0	0.0	0	0.0	0.185		
1	0	0.0	1	1.3			
2	0	0.0	0	0.0			
3	5	3.5	3	3.9			
4	5	3.5	2	2.6			
5	10	7.0	11	14.5			
6	15	10.6	6	7.9			
7	31	21.8	23	30.3			
8	39	27.5	20	26.3			
9	19	13.4	7	9.2			
10	18	12.7	3	3.9			

Notes:

[1] Group differences and 95% confidence intervals (CI) for group differences.

[2] P-value for Chi-Square test

[Source: Tables_BaselineDemo_cat.sas]

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the PS Selected mITT Analysis cohort of 255 patients available for final evaluation. The key safety outcomes for this study are presented below in **Tables 8** to **13.**

Adverse effects that occurred in the PMA clinical study:

The safety results were based on the cohort of TOUCH® CMC 1 Prosthesis subjects (N=149) and the LRTI control subjects (N=76) as presented below. All recorded adverse events for both treatment groups are shown in the following subsections by category, time, and severity. All safety tables in this section are censored at the 24-month follow-up window (up to post-operative day 790). ". The overall adverse event rate was 14.1% for the TOUCH® CMC 1 Prosthesis group and 17.1% for the control group. A higher percentage of adverse events were considered "serious" in the investigational group (4.3%) compared to the control group (1.3%). There were no significant, life-threatening adverse events and the adverse events that did occur were resolved successfully. The single death in the investigational group was not relatable to the device or the procedure.

Table 8: Summary of Adverse Event Rates PS Selected mITT Analysis Set

Date of data transfer 20240301	Touch (N=149)			LRTI (N=76)			Touch vs. LRTI[1]		
	No. of Events	No. of Pts.	% of Pts.	No. of Events	No. of Pts.	% of Pts.	Diff (%)	LB	UB
Any Adverse Event (per patient)	26	21	14.1	15	13	17.1	-3.0	-13.2	7.1
Any Device-Related AE[2]	2	2	1.3						
Any Procedure-Related AE[2]	25	20	13.4	15	13	17.1	-3.7	-13.8	6.4
Any Serious Adverse Event	10	7	4.7	1	1	1.3	3.4	-0.9	7.6
SAE, Device/Procedure-Related	10	7	4.7	1	1	1.3	3.4	-0.9	7.6
SAE, Device-Related	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
SAE, Procedure-Related	10	7	4.7	1	1	1.3	3.4	-0.9	7.6
Secondary Surgical Intervention[3]	9	9	6.0	1	1	1.3	4.7	0.1	9.3
Deaths	1	1	0.7	0	0	0.0	0.7	-0.6	2.0

Notes:

[1] Unadjusted device group differences and 95% binomial confidence interval.

[2] Device or Procedure relatedness includes possibly, probably, and definitely related. Device related only measured in Touch.

[3] Secondary surgical intervention include reoperations, revisions, removals, modifications to any study component or supplemental fixations on the carpometacarpal joint.

[Source: Tables_AE_summary.sas]

Table 9. Summary of TOUCH® Study Adverse Event Rates (PS Selected mITT Analysis Data Set).

	TOUCH® CMC 1 ((N=149)			LRTI (N=76)			TOUCH® CMC 1 vs LRTI[1]		
Specific Adverse Event	**No. of Events**	**No. of Pts.**	**% of Pts.**	**No. of Events**	**No. of Pts.**	**% of Pts.**	**Diff**	**LB**	**UB**
Implant loosening	3	3	2.0	0	0	0.0	2.0	-0.2	4.3
Implant dislocation or migration	2	2	1.3	0	0	0.0	1.3	-0.5	3.2
Implant breakage	0	0	0.0	0	0	0.0	.	.	.
Periprosthetic fracture	0	0	0.0	0	0	0.0	.	.	.
Tendovaginitis de Quervain	8	8	5.4	0	0	0.0	5.4	1.7	9.0
Tendovaginitis stenosans thumb	5	5	3.4	4	4	5.3	-1.9	-7.7	3.9
Tendon rupture	0	0	0.0	0	0	0.0	.	.	.
Pain	2	2	1.3	3	3	3.9	-2.6	-7.4	2.1
Carpal tunnel syndrome	2	2	1.3	0	0	0.0	1.3	-0.5	3.2
Stiffness	2	2	1.3	0	0	0.0	1.3	-0.5	3.2
Wound problems	0	0	0.0	0	0	0.0	.	.	.
Infection	0	0	0.0	0	0	0.0	.	.	.
Complex regional pain syndrome	0	0	0.0	5	5	6.6	-6.6	-12.2	-1.0
FCR tendinitis or (partial=) rupture	0	0	0.0	3	3	3.9	-3.9	-8.3	0.4
Intraoperative trapezium fracture	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
Other	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
Total counts / subjects with at least 1 AE	**26**	**21**		**15**	**13**				

Notes:

[1] 95% binomial confidence interval without PS adjustment.

Adverse Events Requiring Subsequent Surgical Intervention (SSI)

Some adverse events resulted in a subsequent surgical intervention (SSI). Overall, there were nine (9) SSI failures in the TOUCH® group and one (1) SSI failure in the control LRTI group. In the TOUCH® group, 5 SSIs were classified as reoperations, 2 as revisions, and 2 as removals (**Table 10**). Only one SSI in the TOUCH® group was categorized as probably related to the device. The one SSI in the control group was possibly related to the index procedure which resulted in a reoperation for trigger thumb (i.e., tendovaginitis stenosans thumb).

Table 10. TOUCH® Study Subsequent Secondary Surgical Interventions (SSSI).

#	Subject	Description of Complication	Adverse Event Treatment	SSSI Outcome Timepoint / Pain / Satisfaction		
TOUCH® CMC 1						
1	DSG-0016	Intra-operative trapezium fracture	Intra-operative cup revision	2 years	0 / 10	Satisfied
2	DSG-0024	Loose Cup	Implant removal and conversion to RSI arthroplasty.	3 months	0/10 at rest	Satisfied
3	DSG-0044	Implant Loosening.	Implant removal and conversion to LRTI	3 months	N / A	Very satisfied
4	DSG-0054	Implant impingement.	Revision of TOUCH prosthesis, resection of base of metacarpal I and partly distal trapezium, exchange of head/neck components.	N/A	Light pain	Satisfied
5	DSG-0061	Tendovaginitis de Quervain	Release of the 1st extensor compartment and tenosynovectomy of the abductor pollicis longus and extensor pollicis brevis tendons	2 years	1 /10	Very Satisfied
6	DSG-0122	Tendovaginitis de Quervain	Release of the 1st extensor compartment, extension-plasty and tenosynovectomy	2 years	0 /10 at rest	Satisfied
7	DSG-0111	Carpal tunnel syndrome	Open carpal tunnel release	2 years	1 / 10 at rest	Neither satisfied nor not
8	DSG-0026	Carpal tunnel syndrome	Endoscopic carpal tunnel release	2 years	0 / 10 at rest	Very satisfied
9	DSG-0012	Trigger thumb	Open release of the A1 pulley	2 years	1 / 10 at rest	Very satisfied
LRTI						
1	CUAE P-083	Tendovaginitis stenosans thumb	Steroid injection and open release of the A1 pully at 8-months post-op	N/A		

Serious Device-Related Adverse Events

One subject (0.7%) experienced a serious device-related AE (implant loosening) in the TOUCH® group. The device-related SAE occurred between post-operative months 3 and 12 **(Tables 11** and **12).**

Table 11. Summary of TOUCH® Study Serious Adverse Events Rates (PS Selected mITT Analysis Data Set).

	TOUCH® CMC 1 (N=149)			LRTI (N=76)			TOUCH® CMC 1 vs LRTI[1]		
Specific Adverse Event	**No. of Events**	**No. of Pts.**	**% of Pts.**	**No. of Events**	**No. of Pts.**	**% of Pts.**	**Diff**	**LB**	**UB**
Implant loosening	2	2	1.3	0	0	0.0	1.3	-0.5	3.2
Implant dislocation or migration	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
Implant breakage	0	0	0.0	0	0	0.0	.	.	.
Periprosthetic fracture	0	0	0.0	0	0	0.0	.	.	.
Tendovaginitis de Quervain	2	2	1.3	0	0	0.0	1.3	-0.5	3.2
Tendovaginitis stenosans thumb	1	1	0.7	1	1	1.3	-0.6	-3.5	2.2
Tendon rupture	0	0	0.0	0	0	0.0	.	.	.
Pain	2	2	1.3	0	0	0.0	1.3	-0.5	3.2
Carpal tunnel syndrome	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
Stiffness	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
Wound problems	0	0	0.0	0	0	0.0	.	.	.
Infection	0	0	0.0	0	0	0.0	.	.	.
Complex regional pain syndrome	0	0	0.0	0	0	0.0	.	.	.
FCR tendinitis or (partial=) rupture	0	0	0.0	0	0	0.0	.	.	.
Intraoperative trapezium fracture	0	0	0.0	0	0	0.0	.	.	.
Other	0	0	0.0	0	0	0.0	.	.	.
Total counts / subjects with at least 1 AE	**10**	7		**1**	1				
Notes: [1] 95% binomial confidence interval.									

Serious Procedure Related Adverse Events

Table 12 includes all serious procedure-related adverse events by category for both the TOUCH® and LRTI groups. There were 10 events in 7 subjects (4.7%) in the TOUCH® group categorized as a serious procedure-related adverse events.

In the control group, one subject (1.3%) experienced a serious procedure-related adverse event. The greatest number of specific procedure-related AEs were recorded from Month 3 through Month 12 visit.

Table 12: Serious Procedure Related Adverse Events

Date of data transfer 20240301	Touch (I) (N=149)			LRTI (C) (N=76)			I vs C[1]		
Specific Adverse Event	**No. of Events**	**No. of Pts.**	**% of Pts.**	**No. of Events**	**No. of Pts.**	**% of Pts.**	**Diff**	**LB**	**UB**
Implant loosening	2	2	1.3	0	0	0.0	1.3	-0.5	3.2
Implant dislocation or migration	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
Implant breakage	0	0	0.0	0	0	0.0	.	.	.
Periprosthetic fracture	0	0	0.0	0	0	0.0	.	.	.
Tendovaginitis de Quervain	2	2	1.3	0	0	0.0	1.3	-0.5	3.2
Tendovaginitis stenosans thumb	1	1	0.7	1	1	1.3	-0.6	-3.5	2.2
Tendon rupture	0	0	0.0	0	0	0.0	.	.	.
Pain	2	2	1.3	0	0	0.0	1.3	-0.5	3.2
Carpal tunnel syndrome	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
Stiffness	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
Wound problems	0	0	0.0	0	0	0.0	.	.	.
Infection	0	0	0.0	0	0	0.0	.	.	.
Complex regional pain syndrome	0	0	0.0	0	0	0.0	.	.	.
FCR tendinitis or (partial=) rupture	0	0	0.0	0	0	0.0	.	.	.
Intraoperative trapezium fracture	0	0	0.0	0	0	0.0	.	.	.
Other	0	0	0.0	0	0	0.0	.	.	.
Total counts / subjects with at least 1 AE	10	7		1	1				
Notes: [1] Exact 95% binomial confidence interval.									
[Source: Tables_Safety_Serious_PR.sas]									

Radiographic Measurements

Radiographic analysis (TOUCH® CMC 1 group only). included the absence of significant device migration, osteolysis, radiolucencies or fracture on plain X-rays. Because patients in the control LRTI group did not receive an implant, radiographs were not routinely performed obviating meaningful radiographic comparison between the TOUCH® Study groups. Radiographic changes were adjudicated by an independent core radiographic facility selected by Keri Medical.

During the 24-months TOUCH® Study, there were 3 cases of implant migration > 2mm, 30 cases of radiolucent cup lines, and 3 trapezium fractures (**Table 13**). Overall, the rate of radiographic success was high, with 97.9 % of subjects experiencing ≤ 2mm migration, 78.9% without observable peri-implant radiolucencies, and 97.9% were without fracture. Radiolucencies were generally not progressive and did not predict device failure during the 24 months TOUCH® Study.

Table 13: Summary of Radiographic Endpoints PS Selected mITT Analysis Set – TOUCH® (n=149)

Timepoint	Week 6		Month 3		Month 12		Month 24		Timepoint[2]	
	n		n		n		n		n	
Number of subjects	141		73		134		127		142	
Migration of Stem or Cup	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
No	141	100.0	71	97.3	130	97.0	124	97.6	136	95.8
Yes	0	0.0	2	2.7	4	3.0	3	2.4	6	4.2
Migration Grade of Stem or Cup	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Minimal (<=2mm)	0	0.0	2	2.7	2	1.5	2	1.6	3	2.1
Large (>2mm)	0	0.0	0	0.0	2	1.5	1	0.8	3	2.1
Direction of the Migration[1]	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Proximal	0	0.0	2	2.7	3	2.2	2	1.6	5	3.5
Distal	0	0.0	0	0.0	0	0.0	1	0.8	1	0.7
Ulnar	0	0.0	0	0.0	1	0.7	0	0.0	1	0.7
Radial	0	0.0	0	0.0	1	0.7	1	0.8	1	0.7
Radiolucent Line	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
No	115	81.6	58	79.5	109	81.3	106	83.5	112	78.9
Yes	26	18.4	15	20.5	25	18.7	21	16.5	30	21.1
Location of Radiolucent Line	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Proximal at Cup	26	18.4	15	20.5	25	18.7	21	16.5	30	21.1
Distal at stem	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Fracture	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
No	140	99.3	72	98.6	132	98.5	126	99.2	139	97.9
Yes	1	0.7	1	1.4	2	1.5	1	0.8	3	2.1
Localization of Fracture	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Trapezium (proximal)	1	0.7	1	1.4	2	1.5	1	0.8	3	2.1
Metacarpal bone (distal)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Notes:
[1] More than one direction is possible.
[2] Either Month 12 or Month 24

Safety Conclusions

In this study, the TOUCH® device was found to have a reasonable assurance of safety and to be at least as safe as the control LRTI treatment. The overall adverse event rate for the TOUCH® group was lower than the LRTI group, 14.1% vs. 17.1%, respectively. There were no significant, life-threatening adverse events and the adverse events that did occur were able to be successfully resolved.

There were nine (6.0%) SSI failures in the TOUCH® group and one (1.3%) SSI failure in the control LRTI group. In the TOUCH® group, 5 SSIs were classified as reoperations, 2 as revisions, and 2 as removals. Only one SSI in the TOUCH® group was categorized as probably related to the device. The one SSI in the control group was possibly related to the index procedure which resulted in a reoperation for trigger thumb (i.e., tendovaginitis stenosans thumb).

Importantly, all TOUCH® subjects that had the device removed underwent successful subsequent surgeries (either component replacement or conversion toLRTI) with no other adverse events recorded. This demonstrates that a failed TOUCH® implant can be safely and effectively revised with a subsequent standard of care procedure, if needed.

2. Effectiveness Results

The analysis of effectiveness was based on the 255 evaluable patients at the final month time point. Key effectiveness outcomes are presented in **Tables 14 to 18**.

Primary Effectiveness Analysis
The pre-specified analysis of composite clinical success defined in the study was based on the primary analysis cohort, including all TOUCH® CMC 1 treated patients (N=149) and LRTI patients (N=76). Overall, 83.8% of the TOUCH® patients met all four criteria for composite clinical success at 24 months compared to 72.8% of LRTI subjects in the control group at 12-month follow-up.

Table 14: Primary Endpoint Analysis at 24-Month (TOUCH® Group) or 12-Month (LRTI Group)

	TOUCH® CMC 1 Prosthesis			LRTI (Control)			LB 95% CI
	N	n	%	N	n	%	
Composite Clinical Success	115	96.3	83.8%	50	36.4	72.8%	**-3.4%**

Individual Components of the Primary Endpoint

An evaluation of the four individual components of the primary composite endpoint was also performed. A clinically meaningful Improvement in Pain was defined as a decrease in the Numerical Rating Scale (NRS) pain score (during activities) of ≥30% on a 10-point scale. Maintenance or Improvement in Function was defined by key pinch strength which is ≥85% of the subject's pre-operative key pinch strength. Safety success was defined as freedom from subsequent surgical interventions (SSI), or serious, device-related (TOUCH®) or serious procedure related (LRTI) adverse events. **Table 15** demonstrates the investigational treatment (TOUCH®) had similar responder success proportions for individual components of the composite primary endpoint. This analysis was not pre-specified and is presented as descriptive statistics only with confidence intervals.

Table 15: Percentages of TOUCH® Study Subjects Achieving Success (PS Selected mITT Analysis Data Set)

	Touch®[2]			LRTI[2]			Touch® - LRTI[3]		
	N	n	%	N	n	%	Diff (%)	LB	UB
Composite Clinical Success	115	96.3	83.8%	50	36.4	72.8%	11.0	-3.4	25.5
(1) No Secondary Surgical Intervention[4]	149	140.6	94.3%	76	75.2	98.9%	-4.6	-8.5	-0.6
(2) Pain (During Activities) Responder[5]	122	119.1	97.6%	75	68.3	91.1%	6.5	0.3	12.8
(3) Key Pinch Strength Responder[6]	117	108.7	92.9%	49	41.4	84.5%	8.4	-2.1	19.0
(4) No Serious Device- or Procedure-Related AEs[7]	149	142	95.3%	76	75	98.7%			

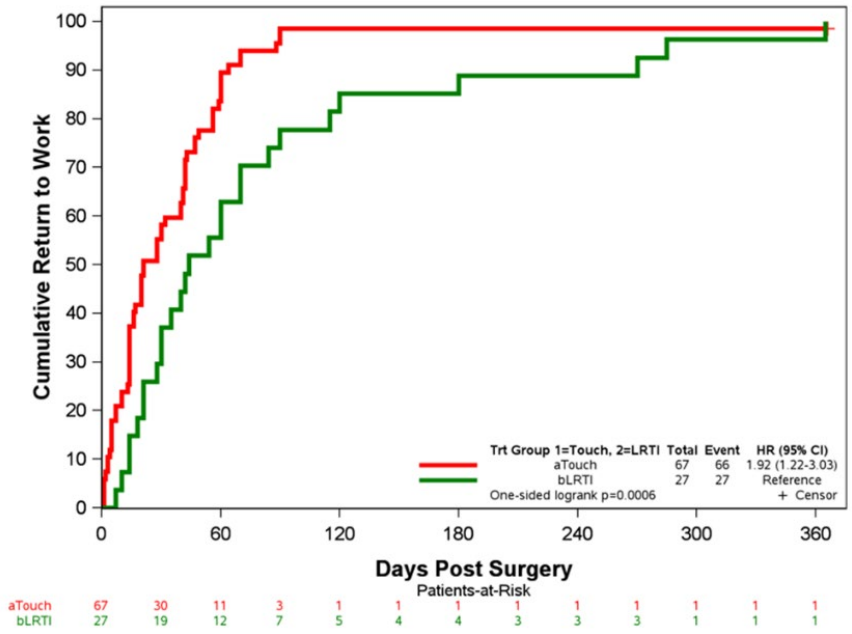
Notes:
[1] The primary ITT (PS Selected) analysis set includes all Touch® subjects (N=149) and 76 controls. 115 of 149 (77.2%) of Touch® and 50 of 76 (65.8%) were evaluable for Month 24 CCS.
[2] LRTI numbers of subjects meeting criterion (n) is computed as the ATT weighted and employment status adjusted success rate multiplied by the actual sample size (N). This results in fractional values for "n". For LRTI, the sum of the ATT weights was 69.6. Touch® numbers of subjects meeting criterion (n) is computed as the ATT weighted (all Touch weights = 1) and employment status adjusted success rate multiplied by the actual sample size (N). The adjustment for employment status results fractional values for "n".
[3] These columns contain the primary ATT estimand and its 90% confidence interval. These were determined as differences in ATT weighted responder rates. The model also controlled for employment status (employed vs not employed) as specified in the PS Design Memo to account for residual bias. The lower bound (LB) of the 90% CI is equivalent to the LB of the 1-sided 95% CI.
[4] Absence of additional surgical intervention, defined as revision, removal, reoperation or supplemental fixation/fusion in a separate surgery subsequent to the index procedure over the initial 24 months.
[5] Pain Responder is defined by a decrease in the Numerical Rating Scale (NRS) pain score of >=30% on a 10-point scale. This is determined at Month 24 for Touch® and Month 12 for LRTI.
[6] Key Pinch Strength Responder is defined by a key pinch strength value of >=85% of pre-op value which reflects maintenance or improvement in function. This is determined at Month 24 for Touch® and Month 12 for LRTI.
[7] At 24 months, absence of a serious device-related or serious procedure-related adverse event for Touch® and absence of a serious procedure-related adverse event for LRTI. Observed data is reported for this row; there were too few events for a meaningful estimation of the weighted group difference and confidence interval.

Secondary Effectiveness Endpoints

Results for secondary endpoints measuring improvements in function, pain, and quality of life patient-reported outcomes were also measured. The results are presented as descriptive statistics only. The secondary endpoint results are summarized in **Table 16**. Improvements in pain and function of the TOUCH® group were reflected in NRS, Kapandji Thumb Opposition Test (or Kapandji Index score) and bMHQ. The TOUCH® group showed greater reductions in pain and greater improvements in function compared to the control group. Patient-reported outcomes including the EQ-5D-5L and EQ-5D-VAS results show general improvement in patient quality of life in both groups.

For those subjects who were employed prior to the index surgery, a time to return to work (RTW) was calculated. In the TOUCH® group, all but one subject returned to work by Month 3. In general, patients treated with the control LRTI procedure were slower to return to work and gradually returned through Month 13, demonstrating a significant benefit for the TOUCH® CMC 1 Prosthesis.

Table 16: Secondary Endpoint Results Summary – PS mITT Analysis Set

Secondary Endpoint – *Mean Scores at Last Follow-Up:*	**TOUCH® (N=149)** ***T=24-Months***	**Control LRTI (N=76)** ***T=12-Months***
Pain During Activities (NRS 10-point scale)		
Total Score	1.1	1.8
Change from Baseline	-6.3	-5.1
% Success (Improvement >=30%)	97.5%	88%
Pain at Rest (NRS 10-point scale)		
Total Score	0.5	0.8
Change from Baseline	-4.7	-3.9
Thumb Function: Key Pinch Strength – (kg)		
Total Score	7.13	4.25
Change from Baseline	2.49	0.43
% Success (Improvement >=85%)	93.3%	77.6%
Thumb Opposition: Kapandji Index		
Total Score	9.8	8.9
Change from Baseline	0.9	0.6
Hand Function: bMHQ		
Total Score	90.3	84.6
Change from Baseline	44.8	36.2
Quality of Life: EQ-5D-5L		
Total Score	0.90	0.89
Change from Baseline	0.17	0.22
Overall Health: EQ-5D-VAS		
Total Score	84.1	79.7
Change from Baseline	10.5	9.8
Time to Return to Work (RTW)		
Cumulative RTW Rate: Month 1	58.2%	37%
Cumulative RTW Rate: Month 2	75%	41.2%
Cumulative RTW Rate: Month 3	85.71%	40%
Cumulative Return to Work Rate up to Month 12	**TOUCH® subjects returned to work quicker**  (Red = TOUCH®, Green = LRTI)	

Additional analyses were performed to demonstrate the TOUCH® patients had clinically meaningful improvements with regards to pain and function.
The original primary endpoint threshold for pain reduction (≥30%) meets the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommended considerations for within-patient minimal clinically meaningful changes in pain (Smith et. a. 2025); **Table 17**, the magnitude of pain relief for all TOUCH® subjects in the primary study cohort with available baseline and 24-month pain data (n=128) are shown. 93% of TOUCH® subjects had a substantial (≥ 50%) pain improvement, with small numbers of patients having moderate (4.7%) or minimally important (1.6%) pain change. There were no patients without any change and only 1 with a pain increase.

Table 17. Magnitude of Pain Relief – TOUCH® Subjects (n=128 with baseline and 24-Month pain)

n (%)	Pain Change	N, Subjects	% Subjects
≥50%	Substantial	119	93%
≥ 30% - <50%	Moderately Important	6	4.7%
≥ 10% - <30%	Minimally Important	2	1.6%
≥ 0% - <10%	No Change	0	0.0%
<0%	Increase	1	0.8%

Table 18 presents the analysis using anchor-based minimal clinically important differences (MCIDs) where possible, to describe the clinical benefits of TOUCH®. There were clinically meaningful benefits shown in pain during activities and at rest, function, and overall health at 2 years.

Table 18. Clinical Benefits Based on Mean Improvement from Baseline Compared to MCIDs

Clinical Benefit	MCID [Reference]	TOUCH®: Mean Improvement (SD) from Baseline	
		Primary Study Group (N=149 at 2 years)	p-Value*
Improvement in Pain During Activities (VAS)	3.9 points [1]	6.3 points (SD 2.3)	p=<0.0001
Improvement in Pain at Rest (VAS)	1.9 points [1]	4.7 points (SD 2.7)	p=<0.0001
Improvement in Function (Key Pinch Strength (kg))	1 kg [2]	2.49 kg (SD 2.46)	p=<0.0001
Improvement in Pain and Function (Brief MHQ)	7 & 16 points [1,3]	44.8 points (SD 19.1)	p=<0.0001
Improvement in Overall Health (EQ-5D-VAS)	8.2 points [4,5]	10.5 points (SD 22.0)	p=0.1020

*p-values from one-sided one-sample t-tests comparing TOUCH® Group to MCID

References for MCIDs:

[1] Marks M, et al. Clinical thresholds of symptoms for deciding on surgery for trapeziometacarpal osteoarthritis. Journal of Hand Surgery (European Volume) 0(0) 1–9, 2019

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[4] Fatima Al Sayah, et al. A Systematic Literature Review of Important and Meaningful Differences in the EQ-5D Index and Visual Analog Scale Scores, Value in Health, Volume 28, Issue 3, 2025, Pages 470-476, ISSN 1098-3015, https://doi.org/10.1016/j.jval.2024.11.006.

3. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

XI. FINANCIAL DISCLOSURE

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included two investigators of which none were full-time or part-time employees of the sponsor and one had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: one investigator
- Significant payment of other sorts: none
- Proprietary interest in the product tested held by the investigator: none
- Significant equity interest held by investigator in sponsor of covered study: one investigator

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

XII. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

This PMA is further supported by supplemental clinical information, collected outside the United States under the device's CE Mark (**Table 19**). These published studies, postmarket clinical follow-up reports, and reports from Switzerland, France, Belgium, Germany, Italy, UK, Austria, and Israel support the conclusions of the TOUCH® Study while generalizing its outcomes to a larger, more diverse patient population.

The clinical evidence includes an additional 880 TOUCH® CMC 1 Prostheses implanted at 16 centers in European Union countries. These published studies enrolled subjects using inclusion/exclusion criteria similar to that of the TOUCH® Study. While the studies use different assessment tools (e.g., Visual Analogue Scale – pain (VAS), Patient-Rated Wrist Evaluation (PRWE), Quick DASH), the authors uniformly report that TOUCH® CMC 1 implantation is associated with clinically meaningful improvements in pain, hand function (key pinch strength), and range of motion. The overall TOUCH® CMC 1 revision rate was 2.5% and the removal rate was 0.1% (22 revisions and 1 removal in 880

devices total) with preliminary clinical data to 8.8 years indicating longer-term device durability and benefit.

Table 19. TOUCH® CMC 1 Clinical Data considered as part of PMA marketing application

#	Reference	Title	Study Design	Subject #	Mean Follow-up
PRIMARY STUDY					
1	P240020	Comparison between TOUCH® CMC 1 prosthesis and trapeziectomy with LRTI: prospective observational cohorts (TOUCH® Cohort Swiss)	Retrospective comparison of prospectively collected data	149 / 79*	2 years TOUCH® / 1-year LRTI
SUPPLEMENTAL STUDIES					
2	Falaise & Boulat 2025 (France)**	Touch® CMC 1 arthroplasty: good outcomes and high survival rate at mean of 6.5 years.	Prospective cohort	58	6.5 years
3	Frey et al. 2025 (Germany)**	TOUCH® duo-mobile prosthesis in TMC osteoarthritis: two-year results and practical insights regarding key surgical steps and complication management.	Retrospective cohort	78	24 months
4	Nietlispach et al. 2025 (Switzerland)**	Which would you choose again? Comparison of trapeziometacarpal implant versus resection arthroplasty in the same patient	Prospective cohorts	14	2.2 years
5	Guzzini et al. 2024 (Italy)	Interposition Arthroplasty versus Dual Cup Mobility Prosthesis in Treatment of Trapeziometacarpal Joint Osteoarthritis	Retrospective cohorts	71 / 65*	24 months
6	Falkner et al. 2024 (Germany)**	Resection arthroplasty versus dual mobility prosthesis in the treatment of trapeziometacarpal joint osteoarthritis	Prospective randomized	22 / 49*	Minimum of 3 years
7	Maling & Rooney, 2024 (UK)	Outcomes of dual-mobility trapeziometacarpal arthroplasties: a systematic review (MAÏA®, Moovis® and Touch® prostheses)	Systematic Review	569	N/A
8	Piccirilli et al. 2024 (Italy)	Comparative Analysis of Prosthetic (Touch®) and Arthroplastic Surgeries for Trapeziometacarpal Arthrosis: Functional Outcomes and Patient Satisfaction With a 2-Year Follow-Up	Prospective cohorts	50 / 50*	2 years
9	Sánchez-Crespo et al. 2024 (Spain)	Experience in major complications with total trapezometacarpal prostheses.	Retrospective observational	38	4 years
10	Van Hove et al. 2024 (Belgium)**	Does trapezium remodeling correlate with cup shape?	Prospective cohorts	53 / 53	1 year
11	Reischenböck et al. 2024 (Switzerland)**	Management of the capsule in trapeziometacarpal joint implant arthroplasty: resection versus repair	Retrospective Registry Review	131/ 57	1 year
12	Herren et al. 2023 (Switzerland)**	Short-term recovery after implant versus resection arthroplasty in trapeziometacarpal joint osteoarthritis	Prospective case series	147 /127*	1 year
13	Tchurukdichian et al. 2023 (France)**	Time to return to work after total trapeziometacarpal prosthesis	Prospective cohort	83	3.5 years
14	Falkner et al. 2023 (Germany)**	Dual mobility prosthesis for trapeziometacarpal osteoarthritis: results from a prospective study of 55 prostheses	Prospective case series	52	25 months
15	Farkash et al. 2023 (Israel)	Failure Rate and Early Complications of Thumb Carpometacarpal Joint Replacement—A Multicenter Retrospective Study of Two Modern Implant Designs	Retrospective cohorts	200	≥ 1 year
16	Van Melkebeke et al. 2022 (Belgium)	Early results of double mobility trapeziometacarpal total joint arthroplasty: prospective series of 82 Touch® prosthesis.	Prospective case series	82	11 months
17	Froschauer et al. 2021 (Austria)	TOUCH® Prosthesis for Thumb Carpometacarpal Joint Osteoarthritis: A Prospective Case Series	Prospective case series	40	12 months
18	Lussiez et al. 2021 (France)	Dual mobility trapeziometacarpal prosthesis: a prospective study of 107 cases with a follow-up of more than 3 years.	Prospective case series	107	40 months
19	Gonzales- Espino et al. 2021 (Belgium)	Touch® double mobility arthroplasty for trapeziometacarpal osteoarthritis: outcomes for 92 prostheses	Retrospective case series	92	1.33 years
POST-MARKET CLINICAL FOLLOW-UP (PMCF) STUDIES					
20	Keri Medical PMCF (France)**	PMCF TOUCH® 2024	Prospective multicenter cohort	196	24.1 months
21	Keri Medical PMCF (France)**	PMCF RETRO 5Y TOUCH®	Retrospective cohort	74	60.7 months

*For comparative studies, the number of TOUCH® CMC 1 is underlined.
**Studies that report co-authors with conflicts of interest or corporate funding.

XIII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Orthopaedic and Rehabilitation Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIV. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

Our evaluation of the cumulative data for the investigational device includes over 1,000 OUS TOUCH® CMC 1 patients derived from the index clinical trial (TOUCH® Study - 149 subjects), 16 published clinical studies from 8 countries, and 2 Keri Medical post-market clinical follow-up reports. These provide a reasonable assurance the device is clinically effective for the treatment of Eaton-Littler stage II/III thumb CMC osteoarthritis and is associated with substantial clinical benefits at 2 years post-implantation:

- Clinically meaningful reduction in pain during activities (mean change from baseline of –6.3 points on the NRS 10-point scale) and at rest (mean change from baseline of –4.7 points on the NRS 10-point scale),
- Maintenance or improvement in hand function (key pinch strength increased mean 2.5kg from baseline),
- Preserved joint range of motion and thumb opposition (Kapandji Index mean change of 0.9 from baseline),
- Improvement in overall quality of life (bMHQ mean change from baseline of 44.8 points, EQ-5D-5L mean change from baseline of 0.17 points, EQ-5D-VAS mean change from baseline of 10.5 points), and
- High patient satisfaction (91.2% to 98.7%).

B. Safety Conclusions

Preclinical testing of the TOUCH® CMC 1 Prosthesis demonstrated that the device design has sufficient strength for the intended use in the first carpometacarpal joint and allows for adequate range of motion. The risks of mechanical failure (wear through liner, component breakage), disassembly, wear debris generation, impingement, and biological hazards are low and consistent with other clinical reports and publications (**Table 19**).

The TOUCH® Study confirmed that the investigational TOUCH® CMC 1 device, when implanted as directed, had low rates of device or procedure-related Serious Adverse Events (SAE) and Subsequent Surgical Interventions (SSI):

- Freedom from Serious Device-Related or Procedure- Related AEs: 99.3% (148/149) of TOUCH® subjects were free from serious device-related adverse events;
- Freedom from SSI: 94.03% (140/149) of TOUCH® subjects were free from subsequent surgical interventions.

The AEs adverse events observed for the 149 TOUCH® investigative subjects during the 2 year TOUCH® Study were similar to those reported in the published literature:

- Implant loosening: 3 subjects (2.0%)
- Implant dislocation or migration: 2 subjects (1.3%)
- Tendovaginitis De Quervain: 8 subjects (5.4%)
- Tenovaginitis stenosans thumb: 5 subjects (3.4%)
- Pain: 2 subjects (1.3%)
- Carpal tunnel syndrome: 2 subjects (1.3%)
- Stiffness: 2 subjects (1.3%)
- Intraoperative trapezium fracture: 1 subject (0.7%)

Based on review of the cumulative clinical data for over 1,000 OUS patients undergoing TOUCH® CMC 1 prosthesis implantation, with the majority of follow-up either two years or longer, the reported frequency of adverse events, serious adverse events, and unfavorable outcomes (e.g., patient dissatisfaction) is acceptably low. Implantation of the TOUCH® CMC 1 Prosthesis does not preclude other subsequent surgical treatments (e.g., LRTI - trapeziectomy and soft-tissue reconstruction) as device revision or removal is technically straight-forward and may be safely performed on an outpatient basis.

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The TOUCH® Study, 16 published clinical studies, and 2 post-market follow-up reports uniformly describe clinically significant beneficial reductions in CMC pain, preserved or improved joint motion and thumb strength (key pinch), and high patient satisfaction associated with TOUCH® CMC 1 implantation.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. These studies and reports document a low incidence of adverse events such as implant failures and subsequent surgical interventions. Observed adverse events generally have highly effective and low risk mitigations (e.g., conversion to a LRTI, release of De Quervain's tenosynovitis).

Additional factors to be considered in determining probable risks and benefits for the TOUCH® CMC 1 Prosthesis device included:

1. The quality of this supporting clinical evidence is diminished by the weaknesses of study designs and statistical methodology (e.g., retrospective,

non-randomized and / or uncontrolled, single-center), the potential for bias (industry-affiliated investigators and co-authors), and concerns with the adequacy of identifying, classifying, and reporting adverse events.

2. The TOUCH® Study, in particular, relied on statistical methods to reduce potentially significant baseline differences between the TOUCH® CMC 1 and the historical LRTI control cohorts (i.e., propensity weighting) that may preclude scientifically valid comparison.
3. Residual uncertainties also remain concerning the performance of the TOUCH® CMC 1 prosthesis when used in the US and the durability (> 5 years) of reported shorter-term outcomes.

However, based on our review of the cumulative data for over 1,000 OUS patients undergoing TOUCH® CMC 1 prosthesis implantation, with the majority of follow-up either two years or longer, the overall benefit-risk profile of the device remains positive (moderate to high benefit / low risk). Residual clinical uncertainties will be reduced by further evaluation of this device in the post-market space (i.e., a US Post-Approval Study).

1. Patient Perspective

Patient perspectives considered during the review included the following patient reported outcome measures as described above:

- Decrease in pain (during activities) in the NRS pain score.
- Decrease in pain (at rest) in the NRS pain score.
- Increase in Hand Function via the bMHQ survey
- Increase in Quality of Life via EQ-5D-5L
- Increase in Overall Health via EQ-5D-VAS

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of the TOUCH® CMC 1 implant when used in accordance with its indications for use. Implantation of the device results in clinically meaningful improvements in hand function and pain with acceptable risks and mitigatable adverse events.

XV. CDRH DECISION

CDRH issued an approval order on July 10, 2025. The final clinical conditions of approval cited in the approval order are described below.

As a condition of approval, the sponsor has agreed to conduct two Post-Approval Studies (PAS) as described 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 US (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 subjects 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)

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.

Secondary endpoints to be assessed are (1) pain at rest; (2) pain during activities,; (3) key pinch (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 composite clinical success 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.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XVI. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

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