FDA 510(k) Premarket Notification

K193312 UNIKO PointCloud™ Knee Instruments

CLEARED

Aug 12, 2020
257 days to decision

K193312 · Product code: **MBH** · Orthopedic
Source: https://www.510kdatabase.net/k193312/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH)
Date received	Nov 29, 2019
Decision date	Aug 12, 2020
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Unik Orthopedics, Inc.**
Location	San Jose, CA, US
Contact	Charlie Chi
510(k) history	2 submissions · 2 cleared · 2020-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k193312/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026