CLEARED

K202022 GMK-SPHERE Tibial inserts FLEX Tibial Insert CR and Resurfacing Patella made of E-CROSS (Vitamin E Highly Crosslinked UHMWPE)

Sep 18, 2020
58 days to decision

K202022 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k202022/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jul 22, 2020
Decision date	Sep 18, 2020
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medacta International S.A.**
Location	Castel San Pietro, CH
Contact	Stefano Baj
Website	https://www.medacta.com
510(k) history	164 submissions · 164 cleared · 2008-2026