FDA 510(k) Premarket Notification

K090988 GMK TOTAL KNEE SYSTEM

CLEARED

Jul 10, 2009
94 days to decision

K090988 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k090988/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Apr 7, 2009
Decision date	Jul 10, 2009
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k090988/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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