FDA 510(k) Premarket Notification

K072857 TOTAL HIP PROSTHESIS SYSTEM QUADRA S + COCRMO FEMORAL BALL HEAD + APRICOT

CLEARED

Feb 4, 2008
122 days to decision

K072857 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k072857/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Oct 5, 2007
Decision date	Feb 4, 2008
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medacta International S.A.**
Location	Castel San Pietro, CH
Contact	PAMELA J WEAGRAFF
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/k072857/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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