FDA 510(k) Premarket Notification

K082792 MEDACTA TOTAL HIP PROSTHESIS SYSTEM - QUADRA H AND R FEMORAL STEMS

CLEARED

Dec 29, 2008
97 days to decision

K082792 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k082792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Sep 23, 2008
Decision date	Dec 29, 2008
Days to decision	97 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/k082792/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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