FDA 510(k) Premarket Notification

K103189 MEDACTA TOTAL HIP PROSTHESIS SYSTEM - AMISTEM C & QUADRA C SHORT NECK

CLEARED

Dec 20, 2010
53 days to decision

K103189 · Product code: **LZO** · Orthopedic
Source: https://www.510kdatabase.net/k103189/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Oct 28, 2010
Decision date	Dec 20, 2010
Days to decision	53 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/k103189/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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