FDA 510(k) Premarket Notification

K242232 Mpact 3D Metal Augments II

CLEARED

Apr 23, 2025
267 days to decision

K242232 · Product code: **LPH** · Orthopedic
Source: https://www.510kdatabase.net/k242232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Jul 30, 2024
Decision date	Apr 23, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Medacta USA**
Contact	Christopher Lussier

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k242232/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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