FDA 510(k) Premarket Notification

K223348 My3D® Personalized Pelvic Reconstruction

CLEARED

Jan 30, 2023
89 days to decision

K223348 · Product code: **LPH** · Orthopedic
Source: https://www.510kdatabase.net/k223348/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Nov 2, 2022
Decision date	Jan 30, 2023
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Onkos Surgical, Inc.**
Location	Parsippany, NJ, US
Contact	Matthew Vernak
510(k) history	4 submissions · 4 cleared · 2016-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k223348/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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