

K212815 My3D® Personalized Pelvic ReconstructionJul 6, 2022
306 days to decisionK212815 · Product code: **LPH** · Orthopedic
Source: <https://www.510kdatabase.net/k212815/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Sep 3, 2021
Decision date	Jul 6, 2022
Days to decision	306 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Onkos Surgical
Location	Parsippany, NJ, US
Contact	Matthew Vernak
510(k) history	6 submissions · 5 cleared · 2020-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212815/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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