FDA 510(k) Premarket Notification

K102080 DEPUY RECLAIM REVISION HIP SYSTEM

CLEARED

Nov 23, 2010
120 days to decision

K102080 · Product code: **LZO** · Orthopedic
Source: https://www.510kdatabase.net/k102080/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Jul 26, 2010
Decision date	Nov 23, 2010
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Depuy(Ireland)**
Location	Cork, IE
Contact	RHONDA MYER
510(k) history	13 submissions · 13 cleared · 2010-2022