CLEARED

Jul 28, 2021
405 days to decision

K201657 Corin Ltd. Hip Products: Trinity™ Acetabular System, Trinity™ PLUS Acetabular Shell, MetaFix™ Hip System, TriFit™ CF and TS Hip Systems, TaperFit™ Hip System, Revival™ Modular Hip System, MiniHip™, Trinity™ Dual Mobility, MobiliT, BiPolar-i, OMNI MOD™ Hip System, OMNI K1 and K2 Hip Systems, OMNI Bipolar Heads, Corin Biolox Delta Ceramic Heads, OMNI Delta Ceramic Heads

K201657 · Product code: **LZO** · Orthopedic
Source: https://www.510kdatabase.net/k201657/

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	Jun 18, 2020
Decision date	Jul 28, 2021
Days to decision	405 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Corin, Ltd.**
Location	Raynham, MA, US
Contact	Christina Rovaldi
510(k) history	2 submissions · 2 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	**BioVera, Inc.**
Contact	Robert A Poggie

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