FDA 510(k) Premarket Notification

K970846 22.2/+4MM CO CR & ZIRCONIA FEMORAL HEAD

CLEARED

Jun 5, 1997
90 days to decision

K970846 · Product code: **LZO** · Orthopedic
Source: https://www.510kdatabase.net/k970846/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Mar 7, 1997
Decision date	Jun 5, 1997
Days to decision	90 days
Third-party review	No

APPLICANT

Company	**Landos, Inc.**
Location	Malvern, PA, US
Contact	KATH LAFFAN
510(k) history	15 submissions · 12 cleared · 1994-1997