FDA 510(k) Premarket Notification

K012800 SYMMETRIC UNICOMPARTMENTAL KNEE SYSTEM

CLEARED

May 3, 2002
255 days to decision

K012800 · Product code: **HRY** · Orthopedic
Source: https://www.510kdatabase.net/k012800/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Semi-constrained, Cemented, Metal/polymer (HRY)
Date received	Aug 21, 2001
Decision date	May 3, 2002
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Whiteside Biomechanics, Inc.**
Location	Creve Coeur, MO, US
Contact	DEBRA MEYER
510(k) history	13 submissions · 12 cleared · 1996-2004

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k012800/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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