FDA 510(k) Premarket Notification

CLEARED

K031823 HEDROCEL VERTEBRAL BODY REPLACEMENT, MODEL 06-172-00XX1

Jul 11, 2003
28 days to decision

K031823 · Product code: **MQP** · Orthopedic
Source: https://www.510kdatabase.net/k031823/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Jun 13, 2003
Decision date	Jul 11, 2003
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Implex Corp.**
Location	Allendale, NJ, US
Contact	MARCI HALEVI
510(k) history	65 submissions · 61 cleared · 1993-2005