FDA 510(k) Premarket Notification

K001709 TROCHANTERIC REATTACHMENT DEVICE (STANDARD) AND (LONG), MODEL 501-066, 501-067

CLEARED

Aug 31, 2000
87 days to decision

K001709 · Product code: **JDQ** · Orthopedic
Source: https://www.510kdatabase.net/k001709/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cerclage, Fixation (JDQ)
Date received	Jun 5, 2000
Decision date	Aug 31, 2000
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pioneer Surgical Technology**
Location	Marquette, MI, US
Contact	AMY H MOMMAERTS
510(k) history	50 submissions · 48 cleared · 1993-2011