FDA 510(k) Premarket Notification

K982914 AESCULAP SPINE SYSTEM EVOLUTION: ADDITIONAL COMPONENTS

CLEARED

Oct 2, 1998
44 days to decision

K982914 · Product code: **MNI** · Orthopedic
Source: https://www.510kdatabase.net/k982914/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Aug 19, 1998
Decision date	Oct 2, 1998
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aesculap, Inc.**
Location	Burlingame, CA, US
Contact	LIA S JONES
510(k) history	207 submissions · 201 cleared · 1991-2025