FDA 510(k) Premarket Notification

K931682 CANNULATED MALLEOLAR SCREW

CLEARED

Apr 5, 1994
365 days to decision

K931682 · Product code: **KWK** · Orthopedic
Source: https://www.510kdatabase.net/k931682/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Appliance, Nail/blade/plate Combination, Single Component (KWK)
Date received	Apr 5, 1993
Decision date	Apr 5, 1994
Days to decision	365 days
Third-party review	No

APPLICANT

Company	**Onyx Medical Corp.**
Location	Memphis, TN, US
Contact	LARAINE B GILMORE
510(k) history	47 submissions · 22 cleared · 1990-1994