FDA 510(k) Premarket Notification

K980781 IMPLEX CONTINUUM KNEE- HEDROCEL REVISION FEMORAL SPACERS

CLEARED

May 22, 1998
81 days to decision

K980781 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k980781/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Mar 2, 1998
Decision date	May 22, 1998
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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