

**K994076 IMPLEX HEDROCEL PS TIBIAL COMPONENT, MODEL
HEDROCEL POSTERIOR STABILIZED TIBIAL COMPONENT
05-XXX-YYYYY**Feb 18, 2000
78 days to decisionK994076 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k994076/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 2, 1999
Decision date	Feb 18, 2000
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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