

K970447 IMPLEX BIPOLAR HIP SYSTEMApr 30, 1997
83 days to decisionK970447 · Product code: **KWY** · Orthopedic
Source: <https://www.510kdatabase.net/k970447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Feb 6, 1997
Decision date	Apr 30, 1997
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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