

**K983128 IMPLEX HEDROCEL REPLACEMENT CUP INSERT  
MODEL NUMBERS 02-246-XXYYY, 02-247-XXYYY,  
02-248-XXYYY**Dec 3, 1998  
86 days to decisionK983128 · Product code: **JDI** · Orthopedic  
Source: <https://www.510kdatabase.net/k983128/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Sep 8, 1998
Decision date	Dec 3, 1998
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983128/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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