

**K963100 TRONZO ACETABULAR FIXATION COMPONENT (1
99-02-00XX (ACE. FIXATION CUP) XX=OD OF ACE. CUP**Feb 12, 1997
187 days to decisionK963100 · Product code: LPH · Orthopedic
Source: <https://www.510kdatabase.net/k963100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Aug 9, 1996
Decision date	Feb 12, 1997
Days to decision	187 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Endotec, Inc.
Location	South Orange, NJ, US
Contact	MICHAEL PAPPAS, PH.D., PE
Website	http://www.endotec.com
510(k) history	15 submissions · 14 cleared · 1991-2009

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