

**K003458 SOFT BEAT FETAL HEART RATE ELECTRODE
MODEL SBT-7000**May 3, 2001
177 days to decisionK003458 · Product code: **HGP** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k003458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Circular (spiral), Scalp And Applicator (HGP)
Date received	Nov 7, 2000
Decision date	May 3, 2001
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Clinical Innovations, Inc.
Location	Murray, UT, US
Contact	DEAN WALLACE
510(k) history	9 submissions · 9 cleared · 1994-2003

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