

K980976 AMEDA DISPOSABLE VACUUM ASSIST CUP WITH FLUID RETENTION TRAP

Aug 21, 1998
158 days to decision

K980976 · Product code: **HDB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k980976/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractor, Vacuum, Fetal (HDB)
Date received	Mar 16, 1998
Decision date	Aug 21, 1998
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hollister, Inc.
Location	Mchenry, IL, US
Contact	JOSEPH S TOKARZ
510(k) history	85 submissions · 78 cleared · 1977-2013

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Device record: <https://www.510kdatabase.net/k980976/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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