

**K011612 MODIFICATION TO HYDROCISION DEBRIDEMENT SYSTEM**Jun 22, 2001  
28 days to decisionK011612 · Product code: **FQH** · General Hospital  
Source: <https://www.510kdatabase.net/k011612/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lavage, Jet (FQH)
Date received	May 25, 2001
Decision date	Jun 22, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hydrocision, Inc.</b>
Location	Hopkinton, MA, US
Contact	DEBBIE IAMPIETRO
510(k) history	12 submissions · 12 cleared · 1998-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011612/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026