

**K012464 HELIX HYDRO-JET**Oct 10, 2001  
70 days to decisionK012464 · Product code: **FQH** · General Hospital  
Source: <https://www.510kdatabase.net/k012464/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Lavage, Jet (FQH)
Date received	Aug 1, 2001
Decision date	Oct 10, 2001
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Andreas Pein Medizintechnik GmbH</b>
Location	Golden, CO, US
Contact	ROBERT N CLARK
510(k) history	1 submissions · 1 cleared · 2001-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012464/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 3, 2026