

K101606 MICROMED PD-8K INSULATION DEFECT DETECTOROct 1, 2010
115 days to decisionK101606 · Product code: **HFG** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k101606/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coagulator, Laparoscopic, Unipolar (and Accessories) (HFG)
Date received	Jun 8, 2010
Decision date	Oct 1, 2010
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mcgan Technology, LLC
Location	Middletown, CT, US
Contact	JACK GANIS
510(k) history	1 submissions · 1 cleared · 2010-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101606/> 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 June 20, 2026