

K182675 Polygon Resection DeviceJan 4, 2019
100 days to decisionK182675 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k182675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Sep 26, 2018
Decision date	Jan 4, 2019
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Polygon Medical, Inc.
Location	Holliston, MA, US
Contact	Ronald Adams
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	R&Q Solutions
Contact	Christine Santagate

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182675/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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