

K243382 RZ Resectoscope SystemJun 3, 2025
215 days to decisionK243382 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k243382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Oct 31, 2024
Decision date	Jun 3, 2025
Days to decision	215 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rz Medizintechnik GmbH
Location	Amsterdam, NL
Contact	Daniela Lang
510(k) history	3 submissions · 3 cleared · 2008-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243382/> 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 14, 2026