

**K201617 TipVision Videoscope System (TipVision VideoScope 0°/30°**Mar 12, 2021  
270 days to decisionK201617 · Product code: **HET** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k201617/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Jun 15, 2020
Decision date	Mar 12, 2021
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EleVision HD 2 Camera Control Unit (CCU))

**APPLICANT**

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Company	<b>Schoelly Fiberoptic GmbH</b>
Location	Ayer, MA, US
Contact	Sandra Baumann
510(k) history	12 submissions · 12 cleared · 1999-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Delphi Medical Device Consulting, Inc.</b>
Contact	Pamela Papineau

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201617/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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