

K180496 TruClear Elite HysteroscopeAug 29, 2018
184 days to decisionK180496 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k180496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Feb 26, 2018
Decision date	Aug 29, 2018
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien
Location	North Haven, CT, US
Contact	Gail Yaeker-Daunis
510(k) history	130 submissions · 126 cleared · 2008-2024

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...

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