

**K160751 Symphion Endoscope and Symphion Cervical Sheath**Jun 14, 2016  
88 days to decisionK160751 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k160751/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Mar 18, 2016
Decision date	Jun 14, 2016
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Boston Scientific</b>
Location	San Jose, CA, US
Contact	BROOKE CUDDY
Website	<a href="http://www.bostonscientific.com/">http://www.bostonscientific.com/</a>
510(k) history	58 submissions · 52 cleared · 2001-2026

Boston Scientific is an American biotechnology and biomedical engineering firm headquartered in Marlborough, Massachusetts. The company manufactures medical devices for interventional specialties including cardiology, endoscopy, urology, and oncology. Boston Scientific has received FDA 510(k) clearances from total submissions since 2001. The company maintains active regulatory engagement, with the latest clearance in 2025. Recent cleared devices span cardiovascular, gastroenterology, urology, orthopedic, and general surgery categories, reflecting broad therapeutic focus. ...

---