

**K002084 MICROVASIVE LITHOTRIPTOR FLEXPLOBE II**Jul 19, 2000  
9 days to decisionK002084 · Product code: **FFK** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k002084/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lithotripter, Electro-hydraulic (FFK)
Date received	Jul 10, 2000
Decision date	Jul 19, 2000
Days to decision	9 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Boston Scientific Corp</b>
Location	San Jose, CA, US
Contact	ROBERT J MICHALIK
Website	<a href="https://www.bostonscientific.com/">https://www.bostonscientific.com/</a>
510(k) history	432 submissions · 411 cleared · 1988-2024

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...