

**K963241 ULTRAFLEX**Nov 14, 1996  
87 days to decisionK963241 · Product code: **JCT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k963241/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Prosthesis, Tracheal, Expandable (JCT)
Date received	Aug 19, 1996
Decision date	Nov 14, 1996
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

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Company	<b>Boston Scientific Corp</b>
Location	San Jose, CA, US
Contact	DANIEL J DILLON
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...

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