FDA 510(k) Premarket Notification

# K962899 ULTRAFLEX DIAMOND

**CLEARED**

May 20, 1997
299 days to decision

K962899 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k962899/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stents, Drains And Dilators For The Biliary Ducts (FGE) |
| Date received | Jul 25, 1996 |
| Decision date | May 20, 1997 |
| Days to decision | 299 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Boston Scientific Corp** |
| Location | San Jose, CA, US |
| Contact | DANIEL J DILLOM |
| Website | https://www.bostonscientific.com/ |
| 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...