

**K981591 VORTEK URETERAL DOUBLE LOOP STENT, BIOSOFT
URETERAL DOUBLE LOOP STENT**Oct 9, 1998
158 days to decisionK981591 · Product code: **FAD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k981591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stent, Ureteral (FAD)
Date received	May 4, 1998
Decision date	Oct 9, 1998
Days to decision	158 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	International Regulatory Consultants
Location	Efrat, Israel, IL
Contact	DONALD F GRABARZ
510(k) history	5 submissions · 5 cleared · 1994-1998

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