

**K030638 DURAMAX .035 BILIARY STENT SYSTEM, MODELS
DML0718-80, DML0718-135, DML0818-80, DML0818-135,
DML0918-80, DML0918-135, DML**Jul 9, 2003
131 days to decisionK030638 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k030638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Feb 28, 2003
Decision date	Jul 9, 2003
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Avantec Vascular Corp.
Location	Sunnyvale, CA, US
Contact	JAMES M SHY
510(k) history	3 submissions · 1 cleared · 2003-2004

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