

K073667 NITI-S BILIARY STENTNov 19, 2008
329 days to decisionK073667 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k073667/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Abbreviated
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 26, 2007
Decision date	Nov 19, 2008
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Taewoong Medical Co., Ltd.
Location	Gyeonggi-Do, KR
Contact	CATHRYN N CAMBRIA
510(k) history	15 submissions · 11 cleared · 2005-2026

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