

K963354 5 STAR MEDICAL ENDOSCOPESep 8, 1997
378 days to decisionK963354 · Product code: **ODF** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mini Endoscope, Gastroenterology-urology (ODF)
Date received	Aug 26, 1996
Decision date	Sep 8, 1997
Days to decision	378 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Five Star Medical, Inc.
Location	Holland, MA, US
Contact	BEVERLY J STEWART
510(k) history	2 submissions · 2 cleared · 1996-1997

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