

K043605 INSCOPE 3-STAGE BALLOON DILATORFeb 4, 2005
36 days to decisionK043605 · Product code: **KNQ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k043605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Esophageal (KNQ)
Date received	Dec 30, 2004
Decision date	Feb 4, 2005
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cordis Europa, N.V.
Location	Warren, NJ, US
Contact	HARM HOVINGA
510(k) history	7 submissions · 5 cleared · 2001-2007

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