

K941391 INFLATABLE RETENTION CUFF SPECULUMOct 20, 1994
212 days to decisionK941391 · Product code: **GBT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k941391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Rectal (GBT)
Date received	Mar 22, 1994
Decision date	Oct 20, 1994
Days to decision	212 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Innovatec Medical Corp.
Location	Duluth, GA, US
Contact	ROY ABELL
510(k) history	1 submissions · 1 cleared · 1994-1994

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