

K943304 3D SURGICAL ENDOSCOPY SYSTEM FOR UROLOGYDec 20, 1995
530 days to decisionK943304 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k943304/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Jul 8, 1994
Decision date	Dec 20, 1995
Days to decision	530 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus America, Inc.
Location	Lake Success, NY, US
Contact	BARRY E SANDS
510(k) history	149 submissions · 149 cleared · 1994-2012

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