

K181994 Single Use Aspiration Needle NA-U201HOct 31, 2018
97 days to decisionK181994 · Product code: **FCG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k181994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Jul 26, 2018
Decision date	Oct 31, 2018
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Medical Systems Corp.
Location	Hachiochi-Shi, JP
Contact	Toshiyuki Nakajima
Website	https://www.olympus-global.com
510(k) history	102 submissions · 102 cleared · 2012-2026

Olympus Medical Systems Corp. is a global medical device manufacturer headquartered in Hachiochi-Shi, Japan. The company specializes in endoscopic imaging systems and therapeutic devices for minimally invasive procedures. Olympus has received FDA 510(k) clearances from total submissions since 2012. The company's regulatory portfolio is dominated by Gastroenterology & Urology devices, including endoscopes, hemostatic forceps, biopsy instruments, and sphincterotomes. The latest clearance in 2026 reflects continued active development and market engagement. Recent cleared dev...

REGULATORY CONSULTANT

Consulting firm	Olympus Surgical Technologies America
Contact	Mary Anne Patella

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k181994/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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