

**K190293 Single Use Cytology Brush BC-205D**Aug 2, 2019  
172 days to decisionK190293 · Product code: **BTG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k190293/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Brush, Biopsy, Bronchoscope (non-rigid) (BTG)
Date received	Feb 11, 2019
Decision date	Aug 2, 2019
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus Medical Systems Corp.</b>
Location	Hachiochi-Shi, JP
Contact	Toshiyuki Nakajima
Website	<a href="https://www.olympus-global.com">https://www.olympus-global.com</a>
510(k) history	101 submissions · 101 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...