

K802187 STERILE DISPOSABLE CYTOLOGY BRUSH

Sep 10, 1980

K802187 · Gastroenterology & Urology

Source: <https://www.510kdatabase.net/k802187/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SP
Submission type	Traditional
Date received	Sep 10, 1980
Decision date	Sep 10, 1980
Third-party review	No

APPLICANT

Company	Olympus Corp.
Location	Mchenry, IL, US
Website	https://www.olympus-global.com
510(k) history	142 submissions · 140 cleared · 1978-1995

Olympus Corp. is a Japanese optics and imaging manufacturer founded in 1919. The company operates from McHenry, US, and holds approximately 70 percent of the global endoscope market. Olympus has received FDA 510(k) clearances from total submissions between 1978 and 1995. The company's cleared devices span gastroenterology, urology, obstetrics, gynecology, and chemistry specialties. This regulatory record reflects the company's historical focus on endoscopic surgical instruments and related technologies. Notable cleared device categories include resection electrodes, fiber...

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Device record: <https://www.510kdatabase.net/k802187/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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