

K925603 OLYMPUS CHOLESTEROL REAGENTFeb 8, 1993
95 days to decisionK925603 · Product code: **CHH** · Chemistry
Source: <https://www.510kdatabase.net/k925603/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzymatic Esterase--oxidase, Cholesterol (CHH) |
| Date received | Nov 5, 1992 |
| Decision date | Feb 8, 1993 |
| Days to decision | 95 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Olympus Corp. |
| Location | McHenry, IL, US |
| Contact | LAURA STORMS-TYLER |
| 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...
