

K153337 Corvocet Biopsy SystemMar 25, 2016
127 days to decisionK153337 · Product code: **KNW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k153337/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Biopsy (KNW) |
| Date received | Nov 19, 2015 |
| Decision date | Mar 25, 2016 |
| Days to decision | 127 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Merit Medical Systems, Inc. |
| Location | South Jordan, UT, US |
| Contact | Ileana Davis |
| Website | https://www.merit.com |
| 510(k) history | 177 submissions · 169 cleared · 1988-2026 |

Merit Medical Systems, Inc. is a leading manufacturer of disposable medical devices for interventional, diagnostic, and therapeutic procedures. Based in South Jordan, the company serves hospitals and physicians worldwide. Merit Medical has established a strong FDA 510(k) regulatory record since its first clearance in 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances span cardiovascular devices, neurology, gastroenterology, and general surgery, demonstrating broad clinical expertise. The latest clearance in 2026 confirms the com...

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