

K230056 MiVu™ Esophageal Endo CapApr 25, 2023
106 days to decisionK230056 · Product code: **QIS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k230056/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Esophageal, Mucosal, Electrical Characterization (QIS) |
| Date received | Jan 9, 2023 |
| Decision date | Apr 25, 2023 |
| Days to decision | 106 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Diversatek Healthcare |
| Location | Highlands Ranch, CO, US |
| Contact | Jim Prinster |
| 510(k) history | 3 submissions · 3 cleared · 2019-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230056/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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