

K252398 SURFLO Hybria Closed System Safety IV CatheterDec 17, 2025
139 days to decisionK252398 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k252398/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ) |
| Date received | Jul 31, 2025 |
| Decision date | Dec 17, 2025 |
| Days to decision | 139 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Terumo Medical Products Hangzhou Co., Ltd. |
| Location | Elkton, MD, US |
| Contact | Tien Trinh |
| 510(k) history | 5 submissions · 5 cleared · 2003-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|-----------------------------------|
| Consulting firm | Terumo Medical Corporation |
| Contact | Tien Trinh |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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