

K142918 EndoTool SubQApr 24, 2015
199 days to decisionK142918 · Product code: **NDC** · General Hospital
Source: <https://www.510kdatabase.net/k142918/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calculator, Drug Dose (NDC) |
| Date received | Oct 7, 2014 |
| Decision date | Apr 24, 2015 |
| Days to decision | 199 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Monarch Medical Technologies |
| Location | Silver Spring, MD, US |
| Contact | STUART LONG |
| 510(k) history | 3 submissions · 3 cleared · 2014-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142918/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026