

K181916 d-Nav SystemFeb 4, 2019
202 days to decisionK181916 · Product code: **NDC** · General Hospital
Source: <https://www.510kdatabase.net/k181916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	Jul 17, 2018
Decision date	Feb 4, 2019
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hygieia, Inc.
Location	Livonia, MI, US
Contact	Kimberly Chaperon
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181916/> 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 June 29, 2026