

K222727 i3 ONE (203100-S)Jun 2, 2023
267 days to decisionK222727 · Product code: **NHV** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k222727/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Water Purification, General Medical Use (NHV)
Date received	Sep 8, 2022
Decision date	Jun 2, 2023
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	i3 TWO connect (203200-S);i3 TWO direct (203300-S)

APPLICANT

Company	I3 Membrane GmbH
Location	Radeberg, DE
Contact	Stephan Brinke-Seiferth
510(k) history	1 submissions · 1 cleared · 2023-2023

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