

K001811 NEU-ION HEMODIALYSIS WATER TREATMENT SYSTEMOct 25, 2000
132 days to decisionK001811 · Product code: **FIP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k001811/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Jun 15, 2000
Decision date	Oct 25, 2000
Days to decision	132 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Neu-Ion, Inc.
Location	Baltimore, MD, US
Contact	LEE A HEIKKINEN
510(k) history	1 submissions · 1 cleared · 2000-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001811/>. 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 30, 2026