

K223258 TNI Clear-Guard™ 3 angled breathing filter (1545020)Jun 15, 2023
237 days to decisionK223258 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k223258/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Oct 21, 2022
Decision date	Jun 15, 2023
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Intersurgical , Ltd.
Location	Berkshire, GB
Contact	Ivan Seniut
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Intersurgical Incorporated
Contact	Kerrie Campbell

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223258/> 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