FDA 510(k) Premarket Notification

**CLEARED**

# K201778 i-STAT TBI Plasma cartridge with the i-STAT Alinity System

Jan 8, 2021
192 days to decision

K201778 · Product code: **QAT** · Immunology
Source: https://www.510kdatabase.net/k201778/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Brain Trauma Assessment Test (QAT) |
| Date received | Jun 30, 2020 |
| Decision date | Jan 8, 2021 |
| Days to decision | 192 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Abbott Laboratories** |
| Location | Abbott Park, IL, US |
| Contact | Brian Ma |
| Website | http://www.abbott.com |
| 510(k) history | 883 submissions · 868 cleared · 1976-2026 |

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...