

K253840 STEDI Scan Device

Jul 22, 2026  
233 days to decision

K253840 · Product code: QAF · Neurology  
Source: <https://www.510kdatabase.net/k253840/>

SUBMISSION DETAILS

|                       |                                         |
|-----------------------|-----------------------------------------|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Impedance Plethysmograph, Cranial (QAF) |
| Date received         | Dec 1, 2025                             |
| Decision date         | Jul 22, 2026                            |
| Days to decision      | 233 days                                |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

APPLICANT

|                |                                       |
|----------------|---------------------------------------|
| Company        | Stroke DX                             |
| Location       | Culver City, CA, US                   |
| Contact        | Richard Lilly                         |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |