

K823494 TOTAL IGE-FAST TESTJan 14, 1983
52 days to decisionK823494 · Product code: **DGC** · Immunology
Source: <https://www.510kdatabase.net/k823494/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Nov 23, 1982
Decision date	Jan 14, 1983
Days to decision	52 days
Third-party review	No

APPLICANT

Company	Axonics, Inc.
Location	Walker, MI, US
510(k) history	5 submissions · 5 cleared · 1983-1985

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Device record: <https://www.510kdatabase.net/k823494/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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