

K181473 DENV Detect NS1 ELISAAug 27, 2018
84 days to decisionK181473 · Product code: **QCU** · Microbiology
Source: <https://www.510kdatabase.net/k181473/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dengue Virus Antigen Assay (QCU)
Date received	Jun 4, 2018
Decision date	Aug 27, 2018
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	InBios International, Inc.
Location	Seattle, WA, US
Contact	Estela Raychaudhuri
510(k) history	7 submissions · 5 cleared · 2014-2025

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