

**K182046 Tyson Bio HS100 Blood Glucose Monitoring System,
Tyson Bio HS100-B Blood Glucose Monitoring System**Nov 30, 2018
122 days to decisionK182046 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k182046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Jul 31, 2018
Decision date	Nov 30, 2018
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tyson Bioresearch, Inc.
Location	Washington, DC, US
Contact	Vance Chang
510(k) history	13 submissions · 13 cleared · 2006-2018

REGULATORY CONSULTANT

Consulting firm	Dynamic Biotech, Inc. Dba. Ivdd Regulatory Consultant
Contact	Feng-Yu Lee

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

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