

**K182047 Tyson Bio HT100-A Blood Glucose Monitoring System**Nov 29, 2018  
121 days to decisionK182047 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k182047/>**SUBMISSION DETAILS**

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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 29, 2018
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Tyson Bio HT100-C Blood Glucose Monitoring System

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Dynamic Biotech, Inc. Db. Ivdd Regulatory Consultant</b>
Contact	Feng- Yu Lee

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

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