

K202145 Bigfoot Unity Diabetes Management SystemMay 7, 2021
280 days to decisionK202145 · Product code: **QLG** · Chemistry
Source: <https://www.510kdatabase.net/k202145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitoring System, Factory Calibrated, Not For Use With Automated Insulin Delivery Systems (QLG)
Date received	Jul 31, 2020
Decision date	May 7, 2021
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bigfoot Biomedical, Inc.
Location	Milpitas, CA, US
Contact	Kate Lee
510(k) history	2 submissions · 2 cleared · 2021-2023

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