

K162564 Medisign GH81 Blood Glucose Monitoring System, Medisign GH82 Blood Glucose Monitoring System, Medisign GH83 Blood Glucose Monitoring System, Medisign GH81 BT Blood Glucose Monitoring System, Medisign GH82 BT Blood Glucose Monitoring System, Medisign GH83 BT Blood Glucose Monitoring SystemJun 7, 2017
266 days to decisionK162564 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k162564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Sep 14, 2016
Decision date	Jun 7, 2017
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tianjin Empecs Medical Device Co., Ltd.
Location	Manan-Gu Anyang-Si Gyeonggi-Do, KR
Contact	Chae Chung Lyuel
510(k) history	4 submissions · 4 cleared · 2012-2017

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