

K161533 A1C EZ Glycohemoglobin Analysis SystemJun 16, 2017
379 days to decisionK161533 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k161533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jun 2, 2016
Decision date	Jun 16, 2017
Days to decision	379 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biohermes Co., Ltd.
Location	Wuxi, CN
Contact	Rao Qiangying
510(k) history	1 submissions · 1 cleared · 2017-2017

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