

K232752 Stone Extraction Balloon (VDK-BAL-23-11/13/15-B,VDK-BAL-23-15/18/20-B,VDK-BAL-23-9/12/15-B,VDK-BAL-23-10/13/16-B,VDK-BAL-23-8.5/11.5/15-B,VDK-BAL-23-12/15/18-B,VDK-BAL-23-11/13/15-C,VDK-BAL-23-15/18/20-C,VDK-BAL-23-9/12/15-C,VDK-BAL-23-10/13/16-C,VDK-BAL-23-8.5/11.5/15-C,VDK-BAL-23-12/15/18-C)

Feb 26, 2024
171 days to decision

K232752 · Product code: **GCA** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k232752/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biliary Catheter For Stone Removal That May Also Allow For Irrigation And Contrast Injection (GCA)
Date received	Sep 8, 2023
Decision date	Feb 26, 2024
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Vedkang Medical Science and Technology Co., Ltd.
Location	Changzhou, CN
Contact	Zheng Xinxing
510(k) history	7 submissions · 7 cleared · 2022-2024
