

K232842 Balloon Inflation SystemFeb 29, 2024
168 days to decisionK232842 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k232842/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Sep 14, 2023
Decision date	Feb 29, 2024
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ningbo Hicren Biotechnology Co., Ltd.
Location	Ningbo, CN
Contact	Qian Jia
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Pureid Medical Technology Co., Ltd.
Contact	Raymond Wu

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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