FDA 510(k) Premarket Notification

K232842 Balloon Inflation System

CLEARED

Feb 29, 2024
168 days to decision

K232842 · 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