FDA 510(k) Premarket Notification

K093828 KYPH X HV-R BONE CEMENT

CLEARED

Aug 12, 2010
241 days to decision

K093828 · Product code: **NDN** · Orthopedic
Source: https://www.510kdatabase.net/k093828/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Dec 14, 2009
Decision date	Aug 12, 2010
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	MARY ROSE
Website	https://www.medtronic.com
510(k) history	209 submissions · 208 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k093828/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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