FDA 510(k) Premarket Notification

K102397 KYPHON XPEDE BONE CEMENT

CLEARED

Feb 28, 2011
188 days to decision

K102397 · Product code: **NDN** · Orthopedic
Source: https://www.510kdatabase.net/k102397/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Aug 24, 2010
Decision date	Feb 28, 2011
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic**
Location	Minneapolis, MN, US
Contact	MARY ROSE
Website	http://www.medtronic.com/us-en/index.html
510(k) history	32 submissions · 32 cleared · 2007-2026

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...