

**K831873 BONE SCREW**Aug 12, 1983  
60 days to decisionK831873 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k831873/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 13, 1983
Decision date	Aug 12, 1983
Days to decision	60 days
Third-party review	No

**APPLICANT**

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Company	<b>W.L. Gore &amp; Associates, Inc.</b>
Location	Mchenry, IL, US
Website	<a href="http://www.gore.com/">http://www.gore.com/</a>
510(k) history	163 submissions · 148 cleared · 1980-2025

W.L. Gore & Associates, Inc. is a global materials science company specializing in advanced medical devices. The company operates with a manufacturing facility in McHenry, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 1980. Cardiovascular devices represent a dominant category, including vascular grafts and balloon catheters. Recent clearances also span general surgery, plastic surgery, and gastroenterology applications. The latest FDA 510(k) clearance in 2025 reflects ongoing regulatory activity. W.L. Gore & Associa...

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