

**K122208 EXTERNAL FIXATOR SYSTEM**Dec 20, 2012  
148 days to decisionK122208 · Product code: **NDK** · Orthopedic  
Source: <https://www.510kdatabase.net/k122208/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, External Fixator (with Metallic Invasive Components) (NDK)
Date received	Jul 25, 2012
Decision date	Dec 20, 2012
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Christopher D. Endara</b>
Location	Miami, FL, US
Contact	CHRISTOPHER ENDARA
510(k) history	1 submissions · 1 cleared · 2012-2012

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122208/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 18, 2026