

**K962239 SMART ADJUSTER (SA201)**Jan 10, 1997  
213 days to decisionK962239 · Product code: **LXM** · Physical MedicineSource: <https://www.510kdatabase.net/k962239/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manipulator, Plunger-like Joint (LXM)
Date received	Jun 11, 1996
Decision date	Jan 10, 1997
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sigma</b>
Location	MD, US
Contact	TAMAS BECSE
Website	<a href="http://www.sigmafotbal.cz/">http://www.sigmafotbal.cz/</a>
510(k) history	6 submissions · 6 cleared · 1983-1997

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k962239/> Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026