

**K864310 RYMCO STERILE SINGLE-USE NEEDLE/SINGLE USE  
SYRINGE**Jan 20, 1987  
78 days to decisionK864310 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k864310/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 3, 1986
Decision date	Jan 20, 1987
Days to decision	78 days
Third-party review	No

**APPLICANT**

---

Company	<b>Rymco Ltda</b>
Location	Coral Gables, FL, US
Contact	AND GOUZ
510(k) history	1 submissions · 1 cleared · 1987-1987

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864310/> 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 July 9, 2026