

**K913779 BANDAGE ROLL, GAUZE**Dec 4, 1991  
112 days to decisionK913779 · Product code: **NAB** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k913779/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze / Sponge,nonresorbable For External Use (NAB)
Date received	Aug 14, 1991
Decision date	Dec 4, 1991
Days to decision	112 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Keilei Intl., Inc.</b>
Location	Dover, NJ, US
Contact	ALBERT SHEN
510(k) history	5 submissions · 5 cleared · 1989-1991

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913779/> 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 July 7, 2026