

**K811965 VISITEC NEEDLE RANGE (GASTERUROLOGY)**Aug 25, 1981  
46 days to decisionK811965 · Product code: **FHR** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k811965/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Gastro-urology (FHR)
Date received	Jul 10, 1981
Decision date	Aug 25, 1981
Days to decision	46 days
Third-party review	No

**APPLICANT**

---

Company	<b>Visitec Co.</b>
Location	Walker, MI, US
510(k) history	49 submissions · 49 cleared · 1979-1995

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k811965/> 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 23, 2026