

**K012654 HYGIA HEALTH SERVICES REPROCESSED  
HUNTLEIGH FLOWTRON DVT SLEEVE MODELS DVT10, DVT  
20, DVT 30, DVT 40**Apr 12, 2002  
242 days to decisionK012654 · Product code: **JOW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k012654/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Aug 13, 2001
Decision date	Apr 12, 2002
Days to decision	242 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hygia Health Services, Inc.</b>
Location	Birmingham, AL, US
Contact	GEOFF M FATZINGER
510(k) history	14 submissions · 14 cleared · 2002-2010

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012654/>; 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 24, 2026