178550

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
04/20/2010	.	
	.	
	.	
	.	

The Policy and Steering Committee on Ways and Means (Bennett) recommended the following:

Senate Amendment (with directory and title amendments)

Between lines 3481 and 3482
insert:

(q) *Device manufacturer permit.*—

1. A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is not required if:

a. The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient; or.

178550

b. The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components that are exempt from registration pursuant to s. 499.015(8).

2.~~1.~~ A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.

3.~~2.~~ The department shall adopt rules related to storage, handling, and recordkeeping requirements for manufacturers of medical devices for human use.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:

Delete line 3396

and insert:

Section 90. Paragraphs (a), (g), and (q) of subsection (2) of

================ T I T L E A M E N D M E N T ================
And the title is amended as follows:

Delete line 293

and insert:

Department of Health to adopt rules; revising the list of exemptions from the requirement that certain persons engaged in the manufacture, repackaging, or assembly of medical devices hold a device manufacturer permit; amending s.