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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/13/2010	.	
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The Committee on Health and Human Services Appropriations  
(Gaetz) recommended the following:

**Senate Amendment (with title amendment)**

Between lines 1528 and 1529  
insert:

Section 15. Paragraph (q) of subsection (2) of section  
499.01, Florida Statutes, is amended to read:

499.01 Permits.—

(2) The following permits are established:

(q) *Device manufacturer permit.*—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



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13 if:

14 1. The person does not manufacture, repackage, or assemble  
15 any medical devices or components for such devices, except those  
16 devices or components which are exempt from registration  
17 pursuant to s. 499.015(8); or

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

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

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

27  
28 ===== T I T L E A M E N D M E N T =====

29 And the title is amended as follows:

30 Delete line 80

31 and insert:

32 criminal conduct; amending s. 499.01, F.S.; exempting  
33 certain persons from requirements for medical device  
34 manufacturer permits; providing an effective date.