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LEGISLATIVE ACTION

Senate

House

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Floor: 11/AD/2R
04/29/2010 11:53 AM

Senator Bennett moved the following:

Senate Amendment (with title amendment)

Between lines 648 and 649
insert:

Section 17. 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*.—

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:



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14 a. The person is engaged only in manufacturing,
15 repackaging, or assembling a medical device pursuant to a
16 practitioner's order for a specific patient; or-
17 b. The person does not manufacture, repackage, or assemble
18 medical devices or components for such devices, except for
19 devices or components that are exempt from registration under s.
20 499.015(8).

21 ~~2.1.~~ 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 ~~3.2.~~ 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 91

31 and insert:

32 employee; amending s. 499.01, F.S.; revising the list
33 of exemptions from the requirement that certain
34 persons engaged in the manufacture, repackaging, or
35 assembly of medical devices hold a device manufacturer
36 permit; providing appropriations from the General