HOUSE AMENDMENT

Bill No. HB 431

Amendment No. 1 (for drafter's use only)

CHAMBER ACTION

Senate	House
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ORIGINAL STAMP BELOW

The Committee on Health Care Licensing & Regulation offered the following:

Amendment (with title amendment)

Remove from the bill: Everything after the enacting clause

and insert in lieu thereof:

Section 1. Subsections (8) and (9) are added to section 499.015, Florida Statutes, 1998 Supplement, to read:

499.015 Registration of drugs, devices, and cosmetics; issuance of certificates of free sale.--

(8) Notwithstanding any requirements set forth in ss. 499.001-499.081, a manufacturer of medical devices that is registered with the United State Food and Drug Administration is exempt from this section and s. 499.041(6), if:

(a) The manufacturer's medical devices are approved for marking by, or listed with the United States Food and Drug Administration in accordance with federal law for commercial distributions; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9) However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application for a permit to do business in this state, as required in s. 499.013 and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing and registration by the United States Food and Drug Administration must include:

(a) For Class II devices, a copy of the pre-market notification letter (510K);

(b) For Class III devices, a Federal Drug Administration pre-market approval number;

(c) For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a Federal Drug Administration registration number; or

(d) For a manufacturer of medical devices whose devices are exempt from pre-market approval by the Federal Drug Administration, a Federal Drug Administration registration number.

Section 2. This act shall take effect July 1, 1999.

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

And the title is amended as follows:

On page 1, lines 1-11,

remove everything in the title of the bill:

and insert in lieu thereof:

A bill to be entitled

An act relating to the registration of drugs, devices, and cosmetics; amending s. 499.015,

F.S.; exempting from ss. 499.015, 499.041 (6), F.S., manufacturers of medical devices that meet specific requirements of the federal Food and Drug Administration; requiring certain manufacturer's application for a permit to do business in this state; providing an effective date.