By Senator Burt

16-729-99

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., each manufacturer of medical devices that are approved by, registered with, and listed with the federal Food and Drug Administration; requiring certain information to be submitted with such a manufacturer's application for a permit to do business in this state; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (8) is 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 are approved by, registered with, and listed with the federal Food and Drug Administration is exempt from ss. 499.015 and 499.041(6). However, the manufacturer must submit evidence of such registration, listing, and approval with its application for a permit to do business in this state, as required in s. 499.013. Evidence of approval and registration by the federal 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.

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SENATE SUMMARY

Exempts from the requirements of ss. 499.015 and 499.041(6), F.S., pertaining to the registration of drugs, devices, and cosmetics, each manufacturer of medical devices that are approved by, registered with, and listed with the federal Food and Drug Administration. Requires each such manufacturer to submit certain documents with the manufacturer's application for a permit to do business in this state.