SENATE AMENDMENT

Bill No. SB 1396

Amendment No. 1

CHAMBER ACTION

Senate | House

The Committee on Health, Aging and Long-Term Care recommended the following amendment:

Senate Amendment (with title amendment)

On page 1, lines 19-27, delete those lines

and insert:

(8) Notwithstanding any requirements set forth in ss. 499.001-499.081, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from ss. 499.015 and 499.041(6) if:

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

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

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 federal Food and Drug Administration must include:

================ 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 5-7, delete those lines

and insert:

F.S., manufacturers of medical devices that meet specified requirements of the federal Food and Drug Administration;