# SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based only on the provisions contained in the legislation as of the latest date listed below.)

BILL: SB 1396

SPONSOR: Senator Burt

SUBJECT: Registration of Drugs, Devices, and Cosmetics

DATE: March 8, 1999 REVISED: 03/11/99

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
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| 1. | Munroe | Wilson | HC | Fav/1 amendment |
| 2. | | | | |
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| 5. | | | | |

## I. Summary:

The bill exempts medical device manufacturers whose devices are approved by, registered with, and listed with the United States Food and Drug Administration (FDA) from the biennial registration with the Department of Health of devices that the manufacturer assembles or manufactures in Florida and the device registration fees. The bill requires each medical device manufacturer to submit evidence of approval and registration with the FDA along with the manufacturer's application for a permit to do business in Florida.

This bill amends section 499.015, Florida Statutes, 1998 Supplement.

## II. Present Situation:

Section 510 of the federal Food, Drug and Cosmetic Act requires United States device manufacturers and distributors to annually register their establishments and to file a list of their devices with the United States Food and Drug Administration. Section 201(h) of the federal Food, Drug and Cosmetic Act defines medical device to mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, which is: recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action in or on the body of man or other animals and which does not metabolize for the achievement of any of its primary intended purposes.

Medical devices are subject to general controls and other controls of the federal Food, Drug and Cosmetic Act. General controls are baseline requirements that apply to all medical device manufacturers. Medical devices, unless otherwise exempt, must be properly labeled, and packaged, be approved for marketing by the FDA, meet their labeling claims, and be manufactured under good manufacturing practices, which is a mandated quality assurance system.

The United States Food and Drug Administration has established classifications for approximately 1,700 different generic types of devices and has grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements which apply to them are: Class I (General Controls); Class II (General Controls and Special Controls); and Class III (General Controls and Pre-Market Approval). Most Class I devices are subject to general controls such as requirements for the manufacturer to annually register with and to file a list of their devices with the FDA, and design and manufacture devices under good manufacturing practices.

In addition to general controls, Class II and Class III devices are subject to further requirements including special controls and premarket approval by the FDA. Class II devices include any device for which reasonable assurance of safety and effectiveness can be obtained by the imposition of special labeling requirements, mandatory performance standards, patient registries and postmarket surveillance. Class III devices include devices that may support or sustain human life, are important in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury. Class III devices require premarket approval by the FDA to be marketed (21 CFR Part 814). A premarket notification (510K) is a marketing application submitted to the FDA to demonstrate that the medical device to be marketed is as safe and as effective or substantially equivalent to a legally marketed device that was or is currently on the United States market and that does not require premarket approval (21 CFR Part 807, Subpart E). Class III devices must be submitted for premarket approval by the FDA to evaluate the safety and effectiveness of the devices.

Any person who only manufactures devices according to another person's specifications for commercial distribution by the person initiating specifications, is not required to list those devices with the FDA (21 CFR Part 807, Subpart B, s. 807.20). The FDA's current good manufacturing practice requirements do not apply to manufacturers of components or parts of finished devices (21 CFR Part 820, Subpart A, s. 820.1). "Component" is defined to mean any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device (21 CFR Part 820, Subpart A, s. 820.3).

Florida duplicates the federal requirements for the registration of medical devices. Chapter 499, Florida Statutes, provides for the regulation of drugs, cosmetics and household products by the Department of Health. Part I, ch. 499, F.S., (ss. 499.001-499.081, F.S.) sets forth the Florida Drug and Cosmetic Act. The purpose of this Act is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics. The part provides uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under, the federal Food, Drug, and Cosmetic Act and the applicable portions of the federal Trade Commission Act which prohibits the false advertising of drugs, devices, and cosmetics. The part specifies prohibited acts and requirements for the distribution and manufacture of legend drugs and legend devices by pharmacies, manufacturers, and other entities.

Part I, ch. 499, F.S., defines manufacturer to mean any person who prepares, derives, manufactures, or produces a drug, device, or cosmetic. Section 499.015, F.S., requires any person who manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in Florida

to register the drug, device, or cosmetic every 2 years and pursuant to s. 499.041, F.S., to pay an annual product fee no less than $5 or greater than $15 for each separate and distinct product in package form. The Department of Health has adopted an administrative rule that provides for a two-year registration fee of $20 for each separate and distinct product (64F-12.018(4), Florida Administrative Code). Medical device manufacturers applying for an initial product registration must submit a product label or copy for every product registered, list each separate and distinct product, provide documentation that shows that the product is legal in interstate commerce (such as evidence of a premarket approval or pre-market notification letter (510K) from the FDA), and submit the appropriate fee (64F-12.016, Florida Administrative Code). The Department of Health may issue a certificate of Free Sale on any product that is required to be registered under ch. 499, F.S., to any applicant who requests the certificate and pays a fee of $25. A certificate of Free Sale, a document required by many foreign countries before a product may enter their country, attests to the marketable status of the product in Florida.

Section 499.013, F.S., requires any person who engages in the assembly or manufacture of medical devices for human use to obtain a permit, to annually pay a fee not less than $500 or greater than $600, and to comply with all appropriate state and federal manufacturing practices. Medical device manufacturers must pay a $150 initial application fee for each new permit which requires an onsite inspection.

As part of its review to improve access to investment capital, the Health Technology Industry Advisory Council to Enterprise Florida, Inc., recommended a reduction or elimination of Florida's medical device registration and fee for any device manufactured or assembled in Florida that has been approved by the FDA.

## III. Effect of Proposed Changes:

The bill exempts medical device manufacturers whose devices are approved by, registered with, *and* listed with the FDA from the biennial registration with the Department of Health of devices that the manufacturer assembles or manufactures in Florida and the device registration fee. The bill requires each medical device manufacturer to submit evidence of approval and registration with the FDA along with the manufacturer's application for a permit to do business in Florida which must include: for Class II devices, a copy of the pre-market notification letter (510K); for Class III devices, a FDA pre-market approval number; for a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, the manufacturer's FDA registration number; and for a manufacturer of medical devices whose devices are exempt from pre-market approval by the FDA, the manufacturer's FDA registration number.

The bill will take effect on July 1, 1999.

## IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Subsections 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

## V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

The Department of Health estimates that medical device manufacturers in Florida will avoid approximately $27,500 annually in product registration fees. According to the department, the biennial registration fee is $20 for each separate and distinct product.

B. Private Sector Impact:

The medical device manufacturers in Florida who do not have to register their devices and pay a product fee for devices which have been approved by, registered with, and listed with the FDA may more effectively compete within the health technology industry.

C. Government Sector Impact:

The Department of Health estimates a decrease of $27,500 in revenue it collected from medical device manufacturers in Florida who will no longer be subject to a biennial registration fee for any device that the manufacturer assembles or manufactures in Florida which has been approved by, registered with, and listed with the FDA.

## VI. Technical Deficiencies:

On page 1, lines 20-21, the bill should refer to a manufacturer of medical devices that is registered with the federal Food and Drug Administration and whose devices are approved for marketing by, or listed with the federal Food and Drug Administration for commercial distribution in accordance with federal law. Under federal law, some devices must be approved by the FDA before the devices can be put into commercial distribution. Medical device establishments are required to register with the FDA and must list the devices they have in commercial distribution.

## VII. Related Issues:

On page 2, lines 1-4 of the bill, a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, must submit its FDA registration number as evidence of FDA approval and registration of the finished device. The FDA's current good manufacturing practice requirements do not apply to manufacturers of components or parts of finished devices and the FDA does not issue a registration number for the components of such devices (21 CFR Part 820, Subpart A, s. 820.1). Under the bill, such components will still be subject to registration as a medical device with the Department of Health.

The bill does not expressly require a medical device manufacturer to update any changes in the information it has previously submitted as evidence of approval and registration with the FDA for devices exempt from the state registration and fees along with any subsequent renewal of the manufacturer's permit to do business in Florida.

## VIII. Amendments:

#1 by Health, Aging and Long-Term Care:
Corrects technical glitches in the bill to more clearly state what requirements a medical device manufacturer must meet to be exempt from Florida's device registration requirements and fees. Exempts a manufacturer of medical devices that is registered with the federal Food and Drug Administration if: the manufacturer's devices are approved for marketing by, or listed with the federal Food and Drug Administration for commercial distribution in accordance with federal law; or the manufacturer acts as a subcontractor for another medical devices manufacturer to manufacture components. Requires manufacturers permitted in Florida to update any information previously submitted for the exemption to the medical device registration requirements at the renewal of their permit.