

By Representative Lynn

1                                   A bill to be entitled  
2           An act relating to drugs, devices, and  
3           cosmetics; amending s. 499.015, F.S.; providing  
4           an exemption from state registration  
5           requirements for medical devices registered,  
6           listed, and approved under federal regulations;  
7           requiring certain evidence upon application to  
8           do business in the state; amending s. 499.041,  
9           F.S.; providing an exemption from the annual  
10          product registration fee; providing an  
11          effective date.

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

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15           Section 1. Subsection (8) is added to section 499.015,  
16 Florida Statutes, 1998 Supplement, to read:

17           499.015 Registration of drugs, devices, and cosmetics;  
18 issuance of certificates of free sale.--

19           (8) Notwithstanding any other requirements in ss.  
20 499.001-499.081, medical device manufacturers whose Class II  
21 and Class III devices are approved by and registered and  
22 listed with the United States Food and Drug Administration are  
23 exempt from the provisions of this section and s. 499.041(6).  
24 However, the medical device manufacturer must submit evidence  
25 of such registration, listing, and approval at the time it  
26 submits its application for a permit to do business in the  
27 state, as required in s. 499.013(2)(d), which evidence shall  
28 include:

29           (a) A copy of the premarket notification letter (510K)  
30 for Class II devices;

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1           (b) The premarket approval number for Class III  
2 devices; or

3           (c) The registration number for subcontract medical  
4 device manufacturers who manufacture components of devices for  
5 manufacturers.

6           Section 2. Subsection (6) of section 499.041, Florida  
7 Statutes, is amended to read:

8           499.041 Schedule of fees for drug, device, and  
9 cosmetic applications and permits, investigational drug  
10 applications, product registrations, and free-sale  
11 certificates; trust fund.--

12           (6) A person that is required to register drugs~~7~~  
13 ~~devices,~~ or cosmetic products under s. 499.015 shall pay an  
14 annual product registration fee of not less than \$5 or more  
15 than \$15 for each separate and distinct product in package  
16 form. The registration fee is in addition to the fee charged  
17 for a free-sale certificate. A person that is required to  
18 register devices under s. 499.015 is exempt from paying the  
19 annual product registration fee under this subsection but is  
20 not exempt from paying the free-sale certificate fee.

21           Section 3. This act shall take effect July 1, 1999.

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24   HOUSE SUMMARY

25           Exempts medical devices approved by and registered and  
26 listed with the United States Food and Drug  
27 Administration from state drug, device, and cosmetic  
28 registration requirements. Eliminates annual product  
29 registration fee requirements for persons registering  
30 medical devices in the state.  
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