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 specified requirements of 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. 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 federal Food and Drug Administration is exempt from this section and s. 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.

(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 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.