Market Access

Among regulations governing the medical device industry, the 1990 Safe Medical Devices Act (SMDA) poses a significant challenge. This landmark legislation redefines how medical products are brought to market.

Key provisions of the act require manufacturers of certain high-risk devices to:

- establish a tracking system to notify patients if a product malfunctions;
- include a summary of safety and effectiveness data for medical devices when applying for pre-market clearance, or state that such information is available upon request; and
- submit post-market surveillance protocols for certain implants and other devices.

In addition, hospital facilities and other end-users must report injuries and deaths associated with life-sustaining devices directly to the Food and Drug Administration (FDA) and/or manufacturers. Distributors are now required to file medical device reports. Enforcement procedures have also been strengthened, allowing the FDA to recall products, temporarily suspend certain high-risk devices, and impose fines for violations.

The industry is working with regulatory authorities to ensure that as new legislation is drafted, manufacturers' financial burden under new laws is minimized. The industry is opposed to FDA user fees which are seen as a tax on new medical technology and which could stifle American R&D.

The most significant market entry hurdle is the FDA. Any company that "engages in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use" is required to register with the FDA. Although foreign firms are not required to register, they are encouraged to do so. Registering with the FDA may help place your company in a more opportune position to enter the U.S. market.

To register a company with the FDA requires completion of an "Initial Registration of Medical Devices Establishment" form (FDA 2891). The form is available from the FDA along with an information and instruction booklet. Registration in no way implies FDA approval.