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Medical Device Excise Tax Liability of Foreign Manufacturers Selling into the United States

Since January 1 of this year, the first sale or use in the U.S. of a taxable medical device by a manufacturer, producer or importer thereof has been subject to a 2.3 percent federal excise tax. Adopted over vehement opposition by affected industry groups, there is now an increasing consensus that the tax is flawed due to the significant costs of administration and the heavy compliance burdens it imposes on the medical device industry, which is comprised primarily of small businesses. But the tax has a key role in financing the U.S. health care reform, with an expectation of raising $10 billion over 10 years. In other words, optimists who are waiting for the tax to be repealed need to face the reality that the tax is here to stay until the government has secured an alternative way of securing $10 billion in revenue. As this is unlikely to occur anytime soon, companies need to ensure they are complying with the tax and focus their efforts on not overpaying.

The initial questions for foreign (non-U.S.) manufacturers selling taxable medical devices into the U.S. are: Who is the importer liable for collecting and remitting the tax to the IRS? The foreign manufacturer? The customs broker? The U.S. subsidiary, distributor or end-user? For purposes of these questions, it is important to note that the IRS definition of "importer" applicable to the medical device excise tax is different from the Food & Drug Administration's "importer" definition. For FDA purposes, an importer is generally the party in the U.S. with a financial interest in the product or a U.S. agent designated by a foreign manufacturer or supplier through a specific written agreement between the foreign entity and the U.S. agent and filed with the FDA.

Under the IRS definition, on the other hand, an importer is the person who is the "inducing and efficient cause" – as principal and not as an agent – of the goods being brought into the U.S. for purposes of sale or use by him. If a person bringing a taxable article into the U.S. does not have a proprietary interest in the article, he is not the importer for purposes of the excise tax. Accordingly, if a foreign manufacturer engages a customs broker to import taxable medical devices into the U.S., the customs broker is only the nominal importer and does not have quarterly excise tax filing and remitting responsibility. Instead, the party bearing the risks of a typical merchant importer (i.e., risks associated with shipments in transit and market fluctuations) and/or engaging in U.S. marketing or promotional activities will be liable for the tax.

In the case of a foreign manufacturer that establishes a U.S. subsidiary to market and distribute taxable devices in the U.S., the U.S. subsidiary will be considered "the inducing and efficient cause" of the goods being brought into the U.S. and liable for the tax because the subsidiary is creating a U.S. market for and directly benefitting from the sale of the

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goods in the U.S. The fact that a U.S. intermediary company is used to facilitate importation and is the importer of record will not change this analysis because the intermediary company will only be considered a nominal importer for purposes of the tax.

Where a foreign manufacturer without a U.S. business presence sells taxable medical devices directly to U.S. end-users, such as hospitals purchasing surgical kits for use by physicians in their operating theatres, the U.S. end-user is liable for the tax because it will be considered the "inducing and efficient cause" for the devices being brought into the United States – there exists no other entity or person with a U.S. presence, such as a distributor, that could be considered the direct cause of bringing the goods into the U.S. An importer is taxed on the use of imported taxable devices in the same manner as if they had been the seller.

Foreign manufacturers with U.S. subsidiaries or other U.S. presence need to be aware that there are significant exemptions and exceptions to the medical device excise tax (and elaborate constructive sale price rules) that make planning necessary to avoid overpaying the tax. The one-paragraph statute has already produced pages of confusing regulations and "Interim Guidance" on several issues that the IRS has yet to determine. Accordingly, taxpayers are advised to keep abreast of developments that may affect their liability under the tax.