The agreement continues for five years unless terminated earlier. The term of the agreement automatically renews for additional one-year terms unless one party provides the other party with written notice of termination at least one year prior to the end of the applicable renewal period. The agreement may be terminated by us for any reason upon 180 days' written notice to Vention. In addition, the agreement may be terminated by mutual agreement of the parties, or by either party, with written notice, upon uncured material breach or insolvency of the other party. Upon termination of the agreement, Vention shall, upon our request, manufacture an additional 24 months of continuous supply of IPGs based on the preceding forecast average or such other amount as agreed upon by the parties.

Other Suppliers

We also have other suppliers, including some sole-source suppliers, for certain of our components, with whom we do not have agreements.

Product Liability and Insurance

The manufacture and sale of our products subjects us to the risk of financial exposure to product liability claims. Our products are used in situations in which there is a risk of serious injury or death. We carry insurance policies which we believe to be customary for similar companies in our industry. We cannot assure you that these policies will be sufficient to cover all or substantially all losses that we experience.

We endeavor to maintain executive and organization liability insurance in a form and with aggregate coverage limits that we believe are adequate for our business purposes, but our coverage limits may prove not to be adequate in some circumstances.

Government Regulations

United States

Our products and operations are subject to extensive and rigorous regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and its implementing regulations, guidances, and standards. The FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, promotion, distribution, and production of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. The FDA also regulates the export of medical devices manufactured in the United States to international markets. Any violations of these laws and regulations could result in a material adverse effect on our business, financial condition and results of operations. In addition, if there is a change in law, regulation or judicial interpretation, we may be required to change our business practices, which could have a material adverse effect on our business, financial condition and results of operations.

Under the FFDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness.

Class I devices are those for which safety and effectiveness can be assured by adherence to FDA's "general controls" for medical devices, which include compliance with the applicable portions of the QSR facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are subject to FDA's general controls, and any other "special controls" deemed necessary by FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure, though certain Class II devices are exempt from this premarket review process. When a 510(k) is required, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" to a legally marketed device, which in some cases may require submission of clinical data. A legally marketed device is defined by statute to mean a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device