Nelson Hardiman Successfully Resolves FDA Warning Letter

In 2012, Nelson Hardiman was approached by a medical device distributor that received a warning letter from the Food and Drug Administration (FDA). The FDA alleged that the distributor was acting as a manufacturer, while adulterating the device and promoting it for unapproved "off-label" uses. The warning letter demanded an immediate response and threatened seizure of the business as well as civil monetary penalties. In successfully resolving the matter, Nelson Hardiman engaged the FDA and responded to their allegations by explaining a basic misunderstanding in the distributor's business structure and by providing a corrective action plan to ensure future compliance. The FDA responded positively to the remediation efforts, and requested that the distributor issue a recall correction letter to explain its new business structure. Working closely with the distributor, Nelson Hardiman assisted the distributor in a reorganization of its business to facilitate compliance and in the issuance of the recall correction letter. Meanwhile, Nelson Hardiman also effectively negotiated with the FDA to allow the distributor to continue its operations with minimal disruption in its daily activities.

In April 2013, the FDA completed an evaluation of the distributor's corrective actions and determined that it had successfully addressed the violations contained in the warning letter. In June 2013, the FDA concluded the recall correction letter and has approved of the compliance measures taken by the distributor.

Nelson Hardiman counsels and assists medical device clients with business, regulatory, and strategic challenges. For more information on how the firm can assist with these challenges, contact Harry Nelson (hnelson@nelsonhardiman.com).