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**MEDICAL DEVICE MANUFACTURER NUVASIVE INC.
TO PAY \$13.5 MILLION TO SETTLE FALSE CLAIMS ACT ALLEGATIONS**

Baltimore, Maryland – California-based medical device manufacturer NuVasive Inc. has agreed to pay the United States \$13.5 million to resolve allegations that the company caused health care providers to submit false claims to Medicare and other federal health care programs for spine surgeries by marketing the company’s CoRoent System for surgical uses that were not approved by the U.S. Food and Drug Administration (FDA). The settlement further resolves allegations that NuVasive caused false claims by paying kickbacks to induce physicians to use the company’s CoRoent System.

The settlement was announced by United States Attorney for the District of Maryland Rod J. Rosenstein; Principal Deputy Assistant Attorney General Benjamin C. Mizer, of the Justice Department’s Civil Division; and Special Agent in Charge Nick DiGiulio of the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG); Inspector General Jon Rymer of the U.S. Department of Defense, Office of Inspector General; and Inspector General Patrick E. McFarland of the Office of Personnel Management – Office of Inspector General.

“Health care providers need to be free to make medical decisions without improper influence by material or incentives from manufacturers,” said U.S. Attorney Rod J. Rosenstein of the District of Maryland. “A medical device manufacturer violates the law if it knowingly causes physicians to use its products for purposes that are not medically reasonable and necessary and to bill federal health insurance programs.”

“The Justice Department is committed to holding medical device manufacturers accountable, which includes requiring that they follow all laws designed to ensure that medical devices are safe and effective,” said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department’s Civil Division. “It is also imperative that manufacturers not improperly influence the selection of medical devices in order to ensure that these decisions are based on the needs and interests of patients, not on a physician’s own financial interests.”

“Defrauding Medicare and Medicaid by paying kickbacks to physicians and promoting uses not covered by Federal health care programs will not be tolerated,” said Special Agent in Charge Nick DiGiulio of the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG). “Settlements such as the one entered into today by NuVasive

send a message to the medical device industry that such practices will be closely monitored.”

The United States alleged that between 2008 and 2013, NuVasive promoted the use of the CoRoent System for surgical uses that were not approved or cleared by the FDA, including for use in treating two complex spine deformities, severe scoliosis and severe spondylolisthesis. As a result of this conduct, the United States alleged that NuVasive caused physicians and hospitals to submit false claims to federal health care programs for certain spine surgeries that were not eligible for reimbursement.

The settlement agreement also resolves allegations that NuVasive knowingly offered and paid illegal remuneration to certain physicians to induce them to use the CoRoent System in spine fusion surgeries, in violation of the federal Anti-Kickback Statute. The illegal remuneration consisted of promotional speaker fees, honoraria and expenses relating to physicians’ attendance at events sponsored by a group known as the Society of Lateral Access Surgery (SOLAS). SOLAS was allegedly created, funded and operated solely by NuVasive, despite its outward appearance of independence.

The civil settlement resolves a lawsuit filed under the whistleblower provision of the False Claims Act by Kevin Ryan, a former NuVasive sales representative (*United States ex rel. Kevin Ryan v. NuVasive, Inc.* (D. Md.)). The act permits private parties to file suit on behalf of the United States for false claims and obtain a portion of the government’s recovery. As part of today’s resolution, Mr. Ryan will receive approximately \$2.2 million.

This settlement illustrates the government’s emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by the Attorney General and the Secretary of Health and Human Services. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in this effort is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than \$24.8 billion through False Claims Act cases, with more than \$15.9 billion of that amount recovered in cases involving fraud against federal health care programs.

The federal share of the civil settlement is \$12,583,413.84, and the state Medicaid share of the civil settlement is \$916,586.16. The claims resolved by this settlement are allegations only, and there has been no determination of liability.

United States Attorney Rod J. Rosenstein commended HHS-OIG, the Department of Defense’s Office of the Inspector General and the Office of Personnel Management’s Office of Inspector General, for their work in the investigation and thanked the FDA’s Office of Chief Counsel and Office of Criminal Investigations for their assistance. Mr. Rosenstein also recognized the work of the Civil Division’s Commercial Litigation Branch and the National Association of Medicaid Fraud Control Units in reaching this settlement. Mr. Rosenstein thanked Assistant U.S. Attorney Thomas H. Barnard, Thomas F. Corcoran and Jason D. Medinger, and Senior Trial Counsel Colin Huntley of the U.S. Department of Justice’s Civil Division, who handled this matter.