Quidel Receives 510(k) Clearance of Its Sofia(TM) Fluorescent Immunoassay Analyzer and Influenza A+B FIA Test

October 26, 2011

SAN DIEGO, CA, Oct 26, 2011 (MARKETWIRE via COMTEX) -- **Quidel Corporation (NASDAQ: QDEL)**, a leading provider of rapid diagnostic testing solutions and cell-based virology assays, announced today that it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for the sale of its Sofia(TM) Analyzer and its Sofia Influenza A+B FIA.

Sofia is the brand name for Quidel's next generation immunoassay system. The easy-to-use Sofia Analyzer and Sofia Influenza A+B FIA combine unique software and fluorescent chemistry to yield an automatic, objective result that is readily available on the instrument's screen, in a hard-copy printout, and in a transmissible electronic form that can network via an LIS system to hospital and medical center databases. The Sofia FIA employs advanced lateral flow and immunofluorescence technologies to provide enhanced clinical sensitivity for influenza A and B. The Sofia Analyzer provides for different operational modes to accommodate both small and large laboratories, as well as other features designed to facilitate use in a variety of healthcare settings, including hospitals, medical centers, and small clinics. These features help ensure a reliable, objective, rapid, and accurate diagnostic result.

"We are very pleased with the FDA clearance of our Sofia Analyzer and Sofia Influenza A+B FIA," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "This announcement represents the achievement of a significant milestone, and positions us in the marketplace with a strategically important platform that will provide numerous benefits to healthcare providers and their patients."

The Sofia Influenza A+B Fluorescent Immunoassay is the first in a series of new Quidel immunofluorescent assays for infectious disease and other conditions or disorders that will use the very same Sofia Analyzer. The 510(k) clearance grants Quidel permission to sell both the Sofia Analyzer and the Sofia Influenza A+B FIA in the United States in advance of the upcoming influenza and respiratory disease season. Both the Sofia Analyzer and the Sofia Influenza A+B FIA received the CE Mark in August 2011, and are thus already available for sale in Europe and other ex-U.S. locations, and they are now available for commercial distribution in the United States.

About Quidel Corporation

Quidel Corporation serves to enhance the health and well being of people around the globe through the development of diagnostic solutions that can lead to improved patient outcomes and provide economic benefits to the healthcare system. Marketed under the QuickVue(R), D3(R) Direct Detection and Thyretain(R) leading brand names, as well as under the new Sofia(TM) and Quidel Molecular brands, Quidel's products aid in the detection and diagnosis of many critical diseases and conditions, including influenza, respiratory syncytial virus, Strep A, herpes, pregnancy, thyroid disease and fecal occult blood. Quidel's research and development engine is also developing a continuum of diagnostic solutions from advanced lateral-flow and direct fluorescent antibody to molecular diagnostic tests to further improve the quality of healthcare in physicians' offices and hospital and reference laboratories. For more information about Quidel's and Diagnostic Hybrid's comprehensive product portfolio, visit quidel.com and dhiusa.com .

This press release contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, seasonality, the timing of onset, length and severity of cold and flu seasons, the level of success in executing on our strategic initiatives, our reliance on sales of our influenza diagnostic tests, uncertainty surrounding the detection of novel influenza viruses involving human specimens, our ability to develop new products and technology, adverse changes in the competitive and economic conditions in domestic and international markets, our reliance on and actions of our major distributors, technological changes and uncertainty with research and technology development, including any molecular-based technology, the medical reimbursement system currently in place and future changes to that system, manufacturing and production delays or difficulties, adverse actions or delays in product reviews by the U.S. Food and Drug Administration (the "FDA"), our ability to comply with FDA, environmental and other regulations, our ability to meet unexpected increases in demand for our products, our ability to execute our strategy, including the integration of new companies or technologies, disruptions in the global capital and credit markets, our ability to hire key personnel, intellectual property, product liability, environmental or other litigation, potential required patent license fee payments not currently reflected in our costs, adverse changes in our international markets, potential inadequacy of booked reserves and possible impairment of goodwill, and lower-than-anticipated acceptance, sales or market penetration of our new products. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," and similar words, although some forward-looking statements are expressed differently. The risks described under "Risk Factors" in reports and registration statements that we file with the SEC from time to time should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this press release. We undertake no obligation to publicly release the results of any revision or update of the forward-looking statements, except as required by law.

Quidel Contact:
Quidel Corporation
John M. Radak
Chief Financial Officer
(858) 646-8032

Media and Investors Contact:
Quidel Corporation
Ruben Argueta

(858) 646-8023

SOURCE: Quidel Corporation