

# Exhibit 2002

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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Biomedical Device Consultants &  
Laboratories of Colorado, LLC,

Civil File No. 0:17-cv-03403

Plaintiff,

**DECLARATION OF CRAIG  
WEINBERG IN SUPPORT OF  
MOTION FOR PRELIMINARY  
INJUNCTION**

v.

TA Instruments – Waters, LLC,

Defendant

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I, Craig Weinberg, hereby declare and state as follows:

1. I am the President and CEO of Plaintiff Biomedical Device Consultants & Laboratories of Colorado, LLC (“BDC”). I make this Declaration in connection with BDC’s motion for a preliminary injunction. I have personal knowledge of the matters set forth below and, if called as a witness, I could and would testify as follows.

**Background**

2. I received my Ph.D. in the area of Mechanical Engineering with a focus in cardiovascular fluid dynamics from the University of Colorado in 2003. In early 2011, I began to serve on the US sub-committee and then, as of January of 2015, began serving on the parent international committee ISO/TC 150/SC 2/WG 1, which is the group that creates the international guidance documents for design verification/validation evaluation of heart valves and heart valve repair devices. As a result, I am very familiar with all the commercially available products that are part the functional performance evaluation, both real-time and accelerated, utilized during the verification/validation testing of the

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associated devices.

3. In 2006, I joined BDC as its president. In about February 2008, a team of three people—myself, Benjamin McCloskey, and Dr. Steven Weinberg—began researching and designing a new prosthetic heart valve and venous valve durability testing system. The dedication of a three person research team to this project was a significant investment for BDC. Though BDC currently has five or six employees solely devoted to working on its testing equipment business, back at the time of the invention in 2008, the entire company was only on the order of five full time employees.

4. The nature of BDC's business requires that it make these types of significant investments in research and development. BDC's customers are those that wish to test medical devices, often the medical device manufacturers themselves testing the device to obtain regulatory approval. The medical device industry is an innovative industry—new and improved medical devices enter the market all the time. These new devices often require state of the art testing systems for their evaluation. For example, prosthetic heart valves have seen significant improvements in recent years resulting in larger sizes and different methods of for securing in place within the human body (e.g. transcatheter heart valves). This has required similar innovations in the equipment available to test the valves. Therefore, to stay competitive, BDC must keep pace with the innovation of both its customers and its competitors.

5. Our research, with respect to heart valve durability test equipment, eventually led to the issuance of four patents, U.S. Patent Nos. 8,584,538 (“the ’538 Patent”), 8,627,708 (“the ’708 Patent”), 9,186,224 (“the ’224 Patent”), 9,237,935 (“the

'935 Patent”) (collectively, “the Patents-in-Suit”). I am a named inventor for all four patents.

### **BDC’s Innovative VDT-3600i System is Market Leading Test System**

6. Before the Patents-in-Suit, heart valve durability testing systems on the commercial market used drive motors that resulted in minimal control of the differential pressure rate and spikes associated with valve closure that could result in unnecessary early deterioration of the test valves and potential false test failures. To better manage valve closing dynamics and differential pressure spikes, and thus better comply with the durability testing standards, myself and the co-inventors of the Patents-in-Suit developed a novel test system that placed an excess volume area on the outflow side of a test sample valve. We also developed a method of operating the test system to help control and minimize differential pressure loading and associated spikes.

7. The reduction in differential pressure spikes during closure in the accelerated flow system was further aided by the use of a “compliance chamber.” A compliance chamber is an area usually filled with air or gas within a test system that permits a change in its volume with an associated change in system pressure. In our design, we positioned a compliance chamber downstream of the test sample. It acts similar to a spring and stores pressure in the system during the “drive” phase (the phase the opens the test valve) and then releases it during the “return” phase (the phase that closes the valve).

8. The Patents-in-Suit revolutionized the market for heart valve durability testing systems by providing an accelerated testing device with a compliance chamber on

the outflow side of the valve and a non-symmetrical waveform driving signal. BDC has commercialized the Patents-in-Suit through a product known as the VDT-3600i heart valve durability tester.

9. The VDT-3600i has been a tremendous success. When it was released it was a unique and differentiated product. It was the only testing system on the market that used a non-regular signal input to the drive motor and provided an excess volume area in a return chamber, downstream of the valve to store fluid during the driving phase of the system. This excess volume area and use of a non-regular driving waveform are significant improvements in accelerated test system design. The signal form better controlled the test valve loading and reduced the differential pressure spike while better meeting the test standard for holding a pressure differential across the valve without excessive pressure loading. The excess volume area further provided for storage of pressure which improved our system's ability to test heart valves at an accelerated rate in an efficient and controlled manner.

10. The market for heart valve durability testing systems is highly specialized and therefore is also very small. There are only four competitors in the market. These competitors currently are my company BDC, Defendant TA Instruments-Waters LLC ("TA Instruments"), Dynatek Labs, and ViVitro Labs. When the VDT-3600i was released, the only competitors were Dynatek and ViVitro. Dynatek's system, however, used old, outdated technology. As a result, it was, and is, not considered a viable alternative in the marketplace for the latest valve technology and currently has few sales, if any. Similarly, ViVitro's testing system relies on movement of an artificial heart valve

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