

M2D2 Participation Application

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I. Overview of Product

Please provide a 1 page overview addressing the following topics:

Product Name:

SOLADA™ Magnetic Resonance (MR) Imaging-Guided Interventional (IGI) planning and positioning system

Medical Issue Addressed:

The standard of care that is available after 40 years of using x-ray mammography for breast cancer healthcare is DISAPPOINTING. In the U.S. \$4 billion per year is spent on breast cancer detection and another \$4 billion per year on breast biopsy procedures to confirm diagnosis. (With a negative biopsy rate of up to 80%, over \$3 billion of this cost could be considered 'wasted'.) \$8 Billion more is spent on breast cancer therapy. Patients demand BETTER breast cancer detection and treatment results, and third-party payers (and the U.S. government) demand LOWER healthcare costs.

Breast MRI has been demonstrated as technically superior at detecting early-stage breast cancer. It shows great promise for imaging-based diagnosis and minimally-invasive imaging-guided intervention and therapy, but is presently too costly and not yet clinically practical. Marvel Medtech's Solada™ technology makes MRI-guided breast procedures easier, faster and more certain by using a 'true-3D' intervention planning approach with multi-axis tool positioning and an intuitive graphical user interface. For doctors, it is like using a GPS instead of a map and compass. It simplifies hand-eye coordination, removes guesswork and aims initially to cut procedure time at least 50%.

More importantly, when combined with virtually real-time MRI, imaging-based diagnosis and MR-compatible ablation therapy tools, the Marvel Medtech Solada™ technology will enable the practical capability to provide breast cancer detection, diagnosis and minimally-invasive therapy, potentially in one patient visit.

Technical Description of Device:

Marvel Medtech's initial product consists of the multi-axis 3D IGI positioning apparatus with integrated radio frequency (RF) surface coils for bi-lateral breast imaging, an open patient support platform to allow optimal

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freedom of motion and physician access, and a localization and intervention planning graphical user interface (GUI). This initial product entails manual actuation of the IGI positioning mechanisms rather than robotic actuation (i.e. 3D control vs. interactive 4D control), and “hands-on” control of the biopsy instruments by the physician. Adding MR-compatible remote control actuators and then integrating virtually real-time MR imaging techniques will enable interactive (4D) intervention planning and execution. Development plans then entail adaptation of minimally-invasive ablation therapy probes (cryoablation and/or other ablation technologies) for compatibility with 4D robotic manipulation in the MRI environment.

Current Stage of Product Development:

A third-generation pre-commercial Solada(3D)[™] prototype is presently under development and being prepared for commencement of human clinical evaluations anticipated in 2008. (See Figure 2 in Appendix)

II. Medical Significance – Please limit response to 2 pages; include supporting diagrams or documentation in appendix.

1. Describe the health issue or medical problem that the device intends to address and its hoped-for benefit.

Background: Breast Cancer statistics: Breast cancer is clearly an important cause of morbidity and mortality, and strikes more women worldwide than any other form of cancer. According to the World Health Organization, more than 1.2 million people will be diagnosed with breast cancer worldwide and nearly half a million will die from the disease annually. The chance of developing invasive breast cancer at some time in a woman's life is about 1 in 8 (13%). Women living in North America have the highest rate of breast cancer in the world. Presently in the U.S. an estimated 3.5 million women are living with breast cancer – about 2.5 million with a history of breast cancer diagnosis and treatment, and up to another million who do not yet know they have the disease. The American Cancer Society (ACS) estimated that in 2007 about 240,000 new cases of breast cancer would be diagnosed among women and about 41,000 women and 450 men will die from breast cancer in the U.S.

When detected and treated before it has spread outside of the breast, breast cancer is associated with a greater than 96% survival. However, when detected at a later stage when the cancer has metastasized to distant organs, the five-year survival rates plummet to less than 25%. Thus, until breast cancer can be prevented, the best hope for survival is early detection and effective treatment.

Limitations of legacy breast imaging technologies: X-ray mammography has been the imaging standard for detection of breast cancer since 1969, when specialized mammography equipment first became available for clinical use. Over most of the forty years since, the breast cancer mortality rate per 100,000 women remained largely unchanged (see Figure 1), which suggests that use of mammography has been largely ineffective in lowering death rates from breast cancer. Only recently has the breast cancer mortality rate seen a downward trend, which may be due to factors such as the reduction in use of hormone replacement therapy or increased population awareness of risk factors and subsequent lifestyle changes, etc.

Limitations of mammography are demonstrated by evidence that mammography fails to detect as much as 20 percent of breast cancer in women over 50 and as much as 40 percent in younger women. In addition, mammography involves exposure to radiation, a known carcinogen, and in vitro evidence suggests that breast tissue containing a BRCA gene mutation may be more vulnerable to the ionizing radiation from mammography than normal breast tissue. A more fundamental inherent disadvantage with using x-ray based and ultrasound