

M2D2 Participation Application

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I. Overview of Product

Please provide a 1 page overview addressing the following topics:

NuOrtho Surgical is an orthopedic surgical tool and procedure company focused on Tissue Preservation. Driven to deliver better patient outcomes using patented electrosurgery technology to eliminate tissue necrosis caused by current plasma based RF products.

First Product Name: ACE Probe

Medical Issue Addressed: Cartilage lesions – only 20% of cartilage lesions in the knee are being addressed or corrected today. This is due to current products causing necrosis and killing healthy cartilage. Of the current 1.4 Million knee cases done a year in the US, there are over 1,000,000 cases with that require chondroplasty.

Technical Description of Device: A low energy RF probe used for contouring tissue. The unique attribute is a patented protective sheath to avoid direct energy contact with tissue. Independent data exist (Dr. Ken DeHaven) that showed a 50% healing effect with this sort of procedure.

Current Stage of Product Development

- Prototype designed, needs to be built for 510k filing.

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.

The focus is on Tissue Preservation and the ACE probe is targeted at the unmet need for cartilage lesions in the knee. Maintaining smooth articular cartilage surfaces can delay the onset of Osteoarthritis and those who will need total knee replacements.

2. Describe the device's current status and potential effectiveness in addressing this medical problem. Please attach any supporting work, preliminary data or testing that is relevant in an appendix.

The device and method are patented. The most relevant third party data is from Dr. Ken DeHaven – paper is attached. Dr. DeHaven uses a regular RF probe in a manner similar to ours and produces excellent results. One of our founders Dr. Auge has been performing the procedure with similar results.

Our goal with the ACE probe (design and mechanism of action) is to enable all surgeons to be able to do chondroplasty with ease. Only 20% of cartilage lesions get fixed today as surgeons don't want to cause necrosis.

3. Describe the potential advantages and disadvantages of this product over any existing or emerging products.

The key advantages are:

- ACE probe does NOT cause Necrosis like existing solutions
- Is easy to use for all skill levels
- Causes a healing effect
- CPT codes exist to cover chondroplasty

The major disadvantage of the ACE probe is the time it will take to get to market to provide patients a better option for cartilage lesions.