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| **CATEGORIES** | **KEY ELEMENTS AND ASSUMPTIONS** | **HYPOTHESIS** |
| Business/Market | That we can capture 10% of transplant patients on immunosuppressant drugs  That Medicare and insurance companies would pay for this. | All patients will want to use a device-based treatment in addition to the drugs they are taking.  Medicare/private insurance will pay for it because of the financial incentive. |
| Technology | Our device can dampen the immune system.  Our diagnostic can predict kidney health and rejection and will be better the current clinical standard.  Our diagnostic and device can be done at home. | Focused ultrasound can reduce the necessary inflammatory cytokines to prevent the rejection process. |
| Regulatory | The FDA will approve of a companion device for transplant patients.  The FDA will approve of the diagnostic device for transplant patients. | Demonstrate that the addition of our device is equivalent to existing comparative device. |
| Clinical | Clinicians trust our product enough to recommend or prescribe it  We can improve the clinical outcome | Validate that our combination device is superior to the current standard in preventing rejection. |