BMES 2021 Design Competition Application

Your Title Page MUST Include:

1. Team Name
2. Each Team Members Name
3. Each Team Members BMES ID
4. Each Team Members Email Address
5. Each Team Members Year of Study
6. Each Team Members University
7. Which Track You Are Submitting To

The narrative may not exceed 5 pages in length (single-spaced, 12 point font). Please include any images or links referenced in your narrative in the body of the narrative, NOT as appendices. Please prepare a narrative description that includes the following:

- **Executive summary.** A summary that presents the justification and overall description of the project. See below for additional details.
- **Description of the problem to be solved.** What is the problem you have solved? What is the market and/or industry need that you intend to address?
- **Project objective statement.** How does your team intend to address the problem? How does your final design solve the problem?
- **Documentation of the final design.** Be sure to include applicable standards and a risk analysis.
- **Prototype of the final design.** Paste graphical representations and photographs in the document and, if available, provide a link to a video. **Note:** If the current team was not involved from the beginning, please specify what your team has worked on vs. what progress had been made by others (other students, or others) prior to your involvement.
- **Proof that the design is functional and will solve the problem.** Include evidence such as test data, market research or pre-clinical/clinical trials.
- **Results of a patent search and/or search for prior art, assessment and patentability.** Two excellent resources for this search are [www.uspto.gov](http://www.uspto.gov), and your institution’s technology transfer office. Regarding marketplace competition, what is currently being used to solve the problem and/or what are the anticipated alternate methods that could be in competition with you in the future?
- **Anticipated regulatory pathway (510(k) vs. PMA, etc.).** Consider researching how the FDA has treated analogous devices.
- **Estimated manufacturing costs.** Provide detailed per unit cost breakdown, including volume discount, for components, final assembly, quality assurance, etc.
- **Potential market and impact.** Define the potential market size, selling price, and distribution channels. Who would your customers be (i.e., who will be purchasing the product) and who would the end users be (i.e., who would be using the product). If possible, quantify the number of potential users and the potential impact the product could have (# of people who would benefit from use, etc.)

**What’s in an Executive Summary?**
An executive summary summarizes all of the above and serves as a stand-alone justification for why this idea should be pursued. Be sure to address the essentials, including:

- **Problem:** What is the problem you aim to solve?
- **Solution:** How do you solve it?
- **Competition:** What are alternate methods of solving the problem or anticipated methods that could be in competition with you in the future?
• **Differentiation:** Why will people choose your solution over others?
• **Technical Feasibility:** Have you done it and can it be done?
• **Regulatory:** What FDA approvals will be required?
• **Sales and Marketing:** What is the estimated size of the market (with rationale)? Who is the buyer/customer/user? From whom will they buy it? At what pricing?