Product Design Specification for BME 201 Group 19: Blinking Orbital Prosthesis
(February 6, 2008)

Group Members: Joel Gaston, Hallie Kreitlow, Alison McArton, Ryan Kimmel

Problem Statement: The focus of this project is to design an animated orbital prosthesis. Currently, few attempts have been made to create a mechanism, which allows the prosthesis to blink. The method previously used was running a wire from the contralateral eye muscle into the orbital prosthesis causing the eye to blink with the contralateral impulse. Our team is to design and fabricate a model simulator with prosthesis that blinks. The device used for animation must be small enough to fit inside the eye cavity as well as contain all parts needed for operation.

Client Requirements:

- Orbital prosthesis must be able to perform the animation necessary to simulate a blinking motion
- Mechanism for animation must be entirely self contained and housed in the eye cavity
- Light weight and little to no sound produced by the animation mechanism
- Cost limit $400

1. Design Requirements

The device must meet all of the client requirements

a. *Performance requirements:* The device is meant to provide blinking animation to a prosthetic eye.
b. *Safety:* The device must not be harmful in any way to humans. The device, if put into production, will eventually be fitted into a human eye socket.
c. *Accuracy and Reliability*: The device must be both highly accurate and reliable. It must blink at the same moment the other eye blinks, as well as blink every time an impulse is received.
d. *Life in Service*: Must last for the minimum duration of a 15-hour work day.
e. *Shelf Life*: The device must have a shelf life of at least one year.
f. *Operating Environment*: The device will be housed with the user's eye socket when in use. May be taken out and stored while sleeping. When in use the device will be at a temperature near 98.6° F and standard pressure.
g. *Ergonomics*: The device will be fabricated with no rough edges or points.
h. *Size*: The device can be at most 1 inch in diameter, or .5 in x .5 in x .5 in. This includes device and all necessary components for operation.
i. *Weight*: The apparatus must be very light weight.
j. *Materials*: The device must have a shell or coating that does not irritate or harm human skin. The material (or its casing) must also be smooth.
k. *Aesthetics*, *Appearance, and Finish*: There is no need for the device to be aesthetically pleasing, due to the fact that it will not be visible while in use.

2. Product Characteristics

a. *Quantity*: Only one working prototype. Could be mass produced based on demand and performance.
b. *Target Product Cost*: Unknown at this time

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is required
b. *Customer*: The customer would like a device that is minimally invasive and unobtrusive.
c. *Patient Related Concerns*: The device should not have to be sterilized, as it will be external. The data collected must be stored confidentially, both for the patient's rights and to preserve the objectivity of the study. It should be noted that patient testing is not part of this project.
d. *Competition*: There is little competition for this design. Similar devices have been built in the past, but had different objectives. It should also be noted that all previous attempts have been unsuccessful for mass production.