Project Design Specifications—Blinking Orbital Prosthesis
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Function:
The Orbital Prosthesis will function as a natural, blinking ocular replacement. Machinery will be contained within the prosthesis, which will fit into the ocular cavity behind the acrylic eyepiece. This eyepiece will be held in place by a silicone mold which will gently interface with the skin. The prosthesis should weigh less than 45 g, have a minimum lifespan of three years, and should not cause detrimental physiological effects.

Client Requirements:

- Cost Effective
- Natural Appearance
- Simple Mechanism
- Reliable Blinking Function

Design Requirements:

1) Physical and Operational Characteristics
    a) *Performance requirements* – Must blink on command.
    b) *Safety* – No negative biological effects: no harmful electromagnetic, chemical, or physical components
    c) *Accuracy and Reliability* – Must consistently blink on command.
    d) *Life in Service* – Used daily for 3-4 years.
    e) *Shelf Life* – Not applicable; prostheses are custom made for immediate use.
    f) *Operating Environment* – In contact with skin and adhesive, close proximity to brain may require magnetic connections. Must operate from -40^{o} to 45^{o} C.
    g) *Ergonomics* – Comfortable for extended use, easily maintained, convenient blinking control device.
    h) *Size* – Mechanism contained in 5.5 cm^3 spherical volume.
    i) *Weight* – Less than 45g.
    j) *Materials* – Cost-efficient, no latex, polymethylmethacrylate (PMMA) recommended.
    k) *Aesthetics* – Must maintain natural appearance of eye and surrounding tissue.
2) Production Characteristics
    a) *Quantity* – One prototype device.
    b) *Target Product Cost* – $2000. This includes acrylic eye and blinking mechanism.
3) Miscellaneous

a) *Standards and Specifications* – FDA approval is not required. The device will be considered a "custom device" by the FDA; therefore, FDA review and approval for the use of the device are unnecessary.

b) *Customer* – Individuals in need of an ocular prosthetic.

c) *Patient-related concerns* – Should look realistic to an outside observer, and give the patient confidence in their appearance.

d) *Competition* – Traditional orbital prosthetics, self-lubricating orbital prosthetics (U.S. Patent 5171265.)