

[Your Company Letterhead]

[Date]

[Recipient Name]

[Recipient Title]

[Recipient Organization]

[Recipient Address]

[City, State, Zip Code]

Dear [Recipient Name],

Subject: Request for Product Authorization - [Product Name/Description]

I hope this letter finds you well. We are writing to formally request the authorization of our product, [Product Name], under the [specific FDA regulation or pathway, e.g., 510(k), PMA] process.

Product Overview:

- **\*\*Product Name:\*\*** [Product Name]
- **\*\*Intended Use:\*\*** [Brief description of intended use]
- **\*\*Classification:\*\*** [Product classification, e.g., Class II, Class III]
- **\*\*Submission Date:\*\*** [Date of submission]
- **\*\*Relevant FDA Reference Number:\*\*** [FDA Reference Number]

We have compiled and submitted extensive data demonstrating the product's safety and efficacy, including:

- [Summarize key data points, e.g., clinical study results, manufacturing process, etc.]
- [List any relevant documents submitted with the request, e.g., labeling, instructions for use, etc.]

We believe that [Product Name] will provide significant benefits to [mention the target population or market] and address an important need within the healthcare system.

Attached are the supporting documents for your review. We are eager to discuss further and provide any additional information required to facilitate the authorization process.

Thank you for your attention to this matter. We look forward to your prompt response.

Sincerely,

[Your Name]

[Your Title]

[Your Company Name]

[Your Phone Number]

[Your Email Address]

[Attachments]