

Request for Pre-Market Approval

Date: [Insert Date]

[Your Name]

[Your Position]

[Your Company Name]

[Your Company Address]

[City, State, Zip Code]

Email: [Your Email]

Phone: [Your Phone Number]

[Recipient Name]

[Recipient Position]

[Regulatory Authority Name]

[Regulatory Authority Address]

[City, State, Zip Code]

Dear [Recipient Name],

I am writing to formally request the pre-market approval of our medical device, [Device Name], which is designed to [Brief Description of Device Purpose]. We believe that our device addresses an important medical need and meets the necessary safety and efficacy requirements set forth by [Regulatory Authority].

Enclosed with this letter, you will find the following documents:

- Device Description
- Clinical Data
- Manufacturing Information
- Risk Analysis
- Labeling and Instructions for Use

We kindly request a meeting to discuss this application further and address any queries you may have. Please let us know your available times for this discussion.

Thank you for considering our request. We look forward to your positive response.

Sincerely,

[Your Signature (if sending a hard copy)]

[Your Printed Name]

[Your Position]

[Your Company Name]