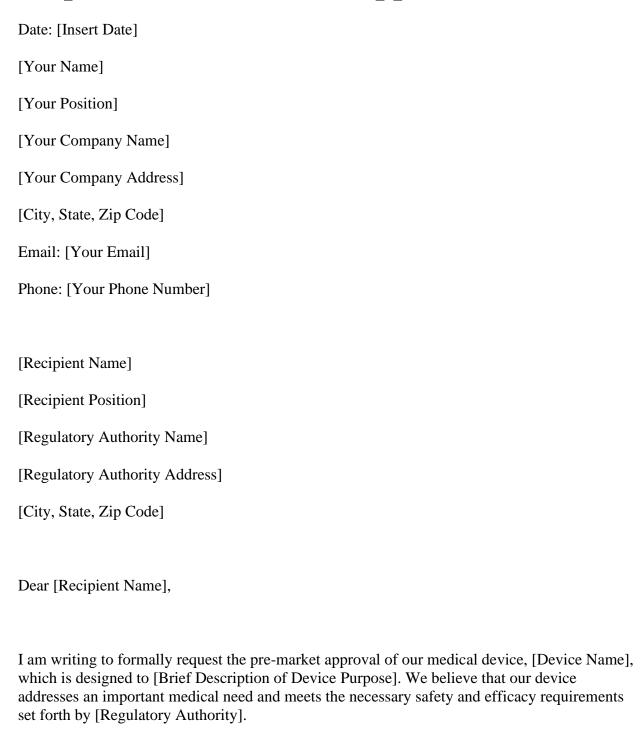
Request for Pre-Market Approval



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]