

Please provide information about your company:

Name of Contact Person: _____

Title of Contact Person: _____

Manufacturer: _____

Street Address: _____

City: _____ **State:** _____ **Country:** _____

Postal Code: _____ **Email Address:** _____

Telephone: _____ **FAX:** _____

Please provide information about your device:

Planned date of submission: _____

Purpose of submission: **New Device** **Additional Indications**

Change in technology, materials, design, or manufacturing process

Other: _____

Product Code: _____ **CFR Section:** _____

Classification Panel: _____

Device Classification: **Class I** **Class II**

Common Name: _____

Trade or Proprietary Name: _____

Name of Legally Marketed Comparison Device: _____

510(k) Control Number: _____

Date Cleared: _____