

**FY 2004 MDUFMA Small Business
Qualification Certification**

Form Approved: [Pending]
Expiration Date: October 1, 2004
OMB Statement: See reverse.

Section I — Information about Yourself

1. Name of entity claiming MDUFMA Small Business status:

2. Federal Employer Identification Number:

3. Address where entity is physically located:

4. Name of person making this Certification:

5. Your telephone number:

(_____) _____
Area Code Telephone Number

6. Your mailing address: Check (✓) if same as item 3.

7. Your e-mail address:

8. What is your relation to the entity claiming MDUFMA Small Business status?

9. Have you listed all of the entity's affiliates, partners, and parent firms on the back (Section II) of this form?

Check (✓) *one* response: Yes The entity identified in item 1
has no affiliates, partners, or parent firms

10. What types of medical device applications do you expect to submit during FY 2004? (Check one, or both.)

Premarket application (BLA, PMA, PDP, PMR, or a supplement) 510(k) notification

11. Complete, sign, and date the following certification:

I certify that _____

Name of entity (must be identical to response to item 1)

(Check *one* response:)

- Has no affiliates, partners, or parent firms.
 Has only the affiliates, partners, and parent firms listed on the back (Section II) of this form

(Check *one* response:)

- Reported "gross receipts or sales" of no more than \$30,000,000 on its most recent Federal income tax return. I have attached a true and accurate copy of the entity's most recent Federal income tax return.
 Together with the affiliates, partners, and parent firms listed on the back of this form, reported total "gross receipts or sales" of no more than \$30,000,000 on their Federal income tax returns. I have attached a true and accurate copy of the entity's most recent Federal income tax return, and a true and accurate copy of the most recent Federal income tax return of each of the entity's affiliates, partners, and parent firms.

I further certify that, to the best of my knowledge, the information I have provided in this MDUFMA Small Business Qualification Certification is complete and accurate. I understand that submission of a false certification may subject me to criminal penalties under 18 U.S.C. 1001 and other applicable federal statutes.

Signature of person making this Certification: _____

Date of this Certification: _____

