DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

PRE-AMENDMENT DEVICE DETERMINATION REQUEST

INSTRUCTIONS: You may use this form to submit documentation to CDRH for the purpose of establishing the pre-amendment (PA) status of a device. A pre-amendment device is one that was in interstate commerce and labeled, promoted and distributed for a specific intended use, prior to May 28, 1976. Interstate commerce does not include plant-to-plant transfers, or devices distributed solely for use in research or for investigational use.

Complete this entire form and sign it. Return the form with documentation and attachments to: ATTN: Pre-amendment Device Determination Request, Office of Compliance, Center for Devices and Radiological Health (CDRH), 10903 New Hampshire Avenue, WO66-3513, Silver Spring, MD 20993-0002. For assistance, call 301-796-5500.

Submitter Name	Company Name
Street Address	Telephone Number
	FAX Number
E-mail Address	Web Site Address

PRE-AMENDMENT DEVICE IDENTIFICATION INFORMATION: Provide as much information as you are aware of about the PA device.

Name of Last Known Manufacturer and Address

Device Brand or Proprietary Name(s)

Earliest Known Date that Product was Placed in Interstate Commerce: _____

PURPOSE OF REQUEST *(Select all that apply)*

- ☐ For use as a predicate device for a 510(k) submission
- ☐ To document PA status for device listing submission
- ☐ To document PA status for customers and FDA staff

DOCUMENTATION METHODS: Select one of the following methods (A, B or C), mark all appropriate check boxes, then attach the relevant documentation, and submit to the address noted above.

☐ **A. Direct proof method:** Submit copies of documents showing device was placed into interstate commerce and was actually labeled and promoted for a specific intended use prior to May 28, 1976. Distribution of device as part of a research study or for investigational use would not be distribution in interstate commerce. Attach as many of the following document types as are available. NOTE: Handwritten dates are generally used only in manufacturing and shipping documents; in other instances dates should be machine printed and original.

Indicate below the document types that are being attached (mark all that are applicable):

- ☐ Dated copies of advertisements
- ☐ Dated copies of catalog pages
- ☐ Dated copies of promotional materials
- ☐ Dated copies of journal articles
- ☐ Dated copies of manufacturing documents
- ☐ Other *(List separately)*
- ☐ Dated copies of shipping documents (invoices, receipts, bills of lading, etc.)

☐ **B. Sworn statements method:** Submission of sworn statements from a current or former employee/company director AND from a credible person who used the device in their clinical practice. Note: If it is not possible to obtain a sworn statement from a current or former employee/company director, then describe your efforts to obtain one and provide sworn statements from two credible users. ***Indicate below the types of sworn statements you are providing (select two statements, including the second):***

☐ A sworn statement from a current or former employee/company director of the firm that distributed the device who is, or was, in a position to be aware of the labeling and promotional information used for the device and to attest that the device was distributed prior to May 28, 1976. The sworn statement should include the following:

- a statement explaining why any invoices or shipping records documenting pre-May 28, 1976 distribution are not available;
- detailed information relating to his/her position and how that placed him/her in a position to be aware of the pre-amendment labeling and promotion of the device;
- a statement that the device was not distributed solely as part of any research study or solely for investigational use prior to May 28, 1976;
- a list of dates of employment with the firm or membership on its board of directors;
- a statement, with any available supporting documentation, of the specific intended uses for which the device was labeled and promoted prior to May 28, 1976. Provide actual copies of any supporting information (e.g., journal article). This supporting information should not reflect the use of the device as part of any research study or for investigational use prior to May 28, 1976; and
- a statement of his/her financial interest in the device and firm.

☐ A sworn statement from a credible person who used the device prior to May 28, 1976. The sworn statement should include the following:

- a statement that the user has personal knowledge that the device entered interstate commerce prior to May 28, 1976;
- the name of the source and the State from which the device was shipped;
- a statement that the device was not received as part of any research study or for investigational use prior to May 28, 1976;
- a statement, with any available supporting documentation, of the specific intended uses for which the device was labeled and promoted prior to May 28, 1976. Provide actual copies of any supporting information (e.g., journal article); and
- a statement of his/her financial interest in the device and firm.

☐ A sworn statement documenting your unsuccessful efforts to obtain a sworn statement from a current or former employee/company director of the firm.

☐ **C. Available information method:** Use this method if you are only able to provide a portion of the information described in item A above. ***If using this method, you must:***

- Provide all available information asked for in item A, and
- Provide as complete a sworn statement as possible from a current or former employee/company director of the firm as described in item B, and
- Provide as complete a sworn statement as possible from a credible user(s) as described in item B.

Note: The key elements that must be addressed by the collective pool of documentation are:

- evidence of interstate commerce (for other than research uses or as part of a plant-to-plant transfer) prior to May 28,1976; and
- evidence of the specific intended use for which the device was labeled/promoted prior to May 28, 1976.

TRUTHFUL AND ACCURATE STATEMENT, SIGNATURE OF SUBMITTER AND DATE SIGNED

I certify that, in my capacity as _____
(position held in company)

of _____,
(company name)

I believe to the best of my knowledge, that all data and information submitted in this request are truthful and accurate and that no material fact has been omitted.

Signature of Submitter	Date *(mm/dd/yyyy)*

Processing Information: Upon receipt of the Pre-amendment Device Determination Request (Form FDA-3752) and supporting documentation, the Office of Compliance (OC) will assign a document tracking number to the request. The request will be forwarded to the appropriate OC staff for review. An "acknowledgment of receipt" letter will be sent to the submitter. The request will generally be assigned to the Office of Compliance Pre-amendment Device Determination Expert for review and issuance of an official FDA determination regarding the status of the device. The determination letter will be mailed to the submitter and posted on the FDA web site. If the request lacks supporting documentation or the Form FDA-3752 is not correctly filled out, a deficiency letter will be issued.