DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DECLARATION FOR IMPORTED ELECTRONIC PRODUCTS SUBJECT TO RADIATION CONTROL STANDARDS

Form Approved OMB No. 0910-0025

INSTRUCTIONS

1. If submitting entries electronically through ACS/ABI, hold FDA-2877 in entry file. Do not submit to FDA unless requested.
2. If submitting paper entry documents, submit the following to FDA:
   a. 2 copies of Customs Entry Form (e.g. CF 3461, CF 3461 Alt, CF 7501, etc.)
   b. 1 copy of FDA 2877
   c. Commercial Invoice(s) in English.

U.S. CUSTOMS PORT OF ENTRY	ENTRY NUMBER	DATE OF ENTRY
Please leave these three fields blank		

NAME & ADDRESS OF MANUFACTURING SITE; COUNTRY OF ORIGIN	NAME & ADDRESS OF IMPORTER & ULTIMATE CONSIGNEE *(if not importer)*

PRODUCT DESCRIPTION	QUANTITY *(Items/Containers)*	MODEL NUMBER(S) & BRAND NAME(S)

DECLARATION: I / WE DECLARE THAT THE PRODUCTS IDENTIFIED ABOVE: ***(Mark X applicable statements, fill in blanks, & sign)***

☐ **A. ARE NOT SUBJECT TO RADIATION PERFORMANCE STANDARDS BECAUSE THEY:**

- ☐ 1. Were manufactured prior to the effective date of any applicable standard; Date of Manufacture _____ .
- ☐ 2. Are excluded by the applicability clause or definition in the standard or by FDA written guidance.
  Specify reason for exclusion _____.
- ☐ 3. Are personal household goods of an individual entering the U.S. or being returned to a U.S. resident. (Limit: 3 of each product type).
- ☐ 4. Are property of a party residing outside the U.S. and will be returned to the owner after repair or servicing.
- ☐ 5. Are components or subassemblies to be used in manufacturing or as replacement parts (NOT APPLICABLE to diagnostic x-ray parts).
- ☐ 6. Are prototypes intended for on going product development by the importing firm, are labeled "FOR TEST/EVALUATION ONLY," and will be exported, destroyed, or held for future testing (i.e., not distributed). (Quantities Limited - see reverse.)
- ☐ 7. Are being reprocessed in accordance with P.L. 104-134 or other FDA guidance, are labeled "FOR EXPORT ONLY," and will not be sold, distributed, or transferred without FDA approval.

☐ **B. COMPLY WITH THE PERFORMANCE STANDARDS** WHICH ARE APPLICABLE AT DATE OF MANUFACTURE AND THAT A CERTIFICATION LABEL OR TAG TO THIS EFFECT IS AFFIXED TO EACH PRODUCT. COMPLIANCE DOCUMENTED IN:

- ☐ 1. Last annual report or Product/Initial report

  _____ ACCESSION NUMBER of Report _____ Name of MANUFACTURER OF RECORD *(Filed report with FDA/CDRH)*

- ☐ 2. Unknown manufacturer or report number; State reason: _____

☐ **C. DO NOT COMPLY WITH PERFORMANCE STANDARDS;** ARE BEING HELD UNDER A TEMPORARY IMPORT BOND; WILL NOT BE INTRODUCED INTO COMMERCE; WILL BE USED UNDER A RADIATION PROTECTION PLAN; AND WILL BE DESTROYED OR EXPORTED UNDER U.S. CUSTOMS SUPERVISION WHEN THE FOLLOWING MISSION IS COMPLETE:

- ☐ 1. Research, Investigations/Studies, or Training (attach Form FDA 766)
- ☐ 2. Trade Show/Demonstration; List dates & use restrictions _____

☐ **D. DO NOT COMPLY WITH PERFORMANCE STANDARDS;** ARE HELD AND WILL REMAIN UNDER BOND; AND WILL NOT BE INTRODUCED INTO COMMERCE UNTIL NOTIFICATION IS RECEIVED FROM FDA THAT PRODUCTS HAVE BEEN BROUGHT INTO COMPLIANCE IN ACCORDANCE WITH AN FDA APPROVED PETITION. *(See Form FDA 766.)*

☐ 1. Approved Petition is attached. ☐ 2. Petition Request is attached. ☐ 3. Request will be submitted within 60 days.

WARNING: Any person who knowingly makes a false declaration may be fined not more than $10,000 or imprisoned not more than 5 years or both, pursuant to Title 18 U.S.C. 1001. Any person importing a non- compliant electronic product may also be subject to civil penalties of $1000 per violation, up to a maximum $300,000 for related violations pursuant to Title 21 U.S.C. 360pp.

SIGNATURE OF IMPORTER OF RECORD

NAME AND TITLE OF RESPONSIBLE PERSON

Public reporting burden for this collection of information is estimated to average 0.2 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
2094 Gaither Road
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.