DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DECLARATION FOR IMPORTED ELECTRONIC PRODUCTS SUBJECT TO RADIATION CONTROL STANDARDS

Form Approved OMB No. 0910-0025
Expiration Date: October 31, 2013

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

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 and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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.

INSTRUCTIONS TO IMPORTERS/BROKERS OF ELECTRONIC PRODUCTS

PURPOSE: The Form FDA 2877 must be completed for electronic products subject to Radiation Control Standards (21 CFR 1010 and 1020-1050) prior to entry into the United States. The local Food and Drug Administration (FDA) district office will review the declaration and notify the importer/agent if the products may be released into U.S. commerce or if they must be held under bond until exported, destroyed, or reconditioned. Until the shipment is released, it may be subject to redelivery for FDA examination.

PAPER OR ELECTRONIC SUBMISSION: Paper entries may be made by submitting the signed original FDA 2877 along with U.S. Customs forms to the local FDA district office; if electronic products are given a MAY PROCEED, a signed copy of CF 3461 will be returned, or if not given a MAY PROCEED, a FDA Notice of Action will be issued. For electronic entries, follow U.S. Customs Service ACS/ABI format and procedures, supported by a signed copy of this form or similar letter. Multiple entries of the same product and model families that are filed electronically may be supported by one form dated not more than 12 months previously.

DECLARATION: Select A, B, C, or D and then select the appropriate number; fill in requested information and sign. For electronic entries, AofC (affirmation of compliance) = RA#, RB#, RC#, or RD# (e.g., Radiation Declaration A5 = RA5). **Transmit model number using AofC code MDL and transmit brand name using FDA line level brand name field. If RA3 or RA6 is selected, you must transmit quantity (number of units) using the Quantity and Unit of Measure Pairs at the FDA line level.**

DECLARATION A: Importers should be prepared to demonstrate compliance to or non-applicability of FDA standards, regulations, or guidance. Components or sub-assemblies must be non-functioning. Products being reprocessed must be exported by the importer, without intermediate transfer of ownership. For RA3 the quantity limit is 3 and for RA6 the limit = 50 units TV products, microwave ovens, and Class 1 laser products limit = 200 units CD-ROM and DVD (digital versatile disc) laser products; see May 14, 1997, notice to industry issued by the Center for Devices and Radiological Health (CDRH).

DECLARATION B: If declaration RB1 is selected, provide the FDA Establishment Identifier (FEI) of the manufacturer who filed the radiation product/abbreviated report to FDA, CDRH, Rockville, Maryland. To transmit the accession number of that report use AofC code ACC. If the manufacturer cannot be determined or located, the importer must be able to provide evidence showing a certification (certifi.) label on each product and state reason: returned to orig exporter or certifi. label evidence. The new AofC codes (RB1, RB2) for this declaration will not be activated until a process is made available to determine the FEI of the responsible firm. Continue to use RAB in electronic transmission until the FEI query is available and industry is notified of its availability.

DECLARATION C: Noncompliant products may be imported only for research, investigations/studies, demonstration or training. They should be used only by trained personnel and under controlled conditions to avoid unnecessary radiation exposure. Product(s) will be detained by the local FDA district office. Since product(s) for which "C" Declarations are made will be under Temporary Import Bond (TIB) or equivalent, ultimate disposition is limited to export or destruction under U.S. Customs supervision when the purpose has been achieved or the length of time stated has expired. For purposes other than demonstration, the Form FDA 766, outlining protections, must be approved by FDA prior to use. The importer/broker must include with the FDA 766:

1. A full description of the subject electronic product(s).
2. The purpose for which the product(s) is being imported.
3. How the product(s) will be used.
4. Where the product(s) will be located.
5. The approximate length of time and dates the product(s) will be in this country.

For product(s) being used for trade shows/demonstrations, list the dates and use restrictions (Form FDA 766 is not required). A sign stating that the product does not comply with FDA performance standards must be displayed and viewable at all times during the use of product(s). All medical products, cabinet x-ray, or Class IIIb and IV lasers may NOT operate (turn on product(s)) at trade shows.

DECLARATION D: Noncompliant products must be brought into compliance with standards under FDA supervision and following a plan approved by FDA. The plan, documented on the Form FDA 766, must address technical requirements, labeling, and reporting. Some plans may need approval by both the CDRH and the local FDA district office. Use of this declaration is limited to occasional shipments; ongoing reconditioning is considered manufacturing that is handled through other means. Product(s) will be detained by the local FDA district office. An FDA 766 must be filed indicating the procedure intended to bring the product into compliance. This procedure will include a satisfactory corrective action plan and/or a product report. The FDA 766 must include all of the information requested under Declaration C. The approximate length of time will be for the amount of time needed to bring product(s) into compliance. Declaration D is also made for failure to provide reports, failure to certify, etc.

If an importer/broker intends to import equipment into the United States for purposes of research, investigation, studies, demonstrations, or training but also wishes to retain the option of bringing the product into compliance with the performance standard, check Declarations C and D on the FDA 2877 and insert the word "or " between the Affirmations. Note: The U.S. Customs Service will treat this entry as a "D" Declaration for purposes of duty. Such requests must be made on the FDA 766; include Items 1, 2, and 3 under Declaration C, a statement of the need to use the option "C" or "D" Declaration, a statement of how the product(s) will be brought into compliance and the approximate length of time necessary to evaluate or demonstrate the product(s) and the time necessary to bring the product(s) into compliance (both actions must be accomplished within the period of time granted by FDA). For electronic entries select Declaration RD3.

Ultimately, product(s) must be brought into compliance with the applicable standard in accordance with a corrective action plan which has been approved by the FDA. If the product(s) are not brought into compliance within the allotted time frame of the approved application and an extension is not requested of, or granted by, the FDA, the local FDA district office shall refuse entry on the shipment and require the product(s) to be either exported or destroyed under U.S. Customs supervision.

If additional guidance is needed, please contact your local FDA district office or consult the following FDA web pages: www.fda.gov/, www.fda.gov/ora/hier/ora_field_names.txt, and http://www.fda.gov/ora/compliance_ref/rpm/.

[Ref: 21 U.S.C. 360mm, 21 CFR 1005, 19 CFR 12.90-12.91.] FDA: CP 7382.007/.007A