Letter to Industry about Import Entry Review Process

Dear Official Correspondent/United States Agent,

The United States Food and Drug Administration (USFDA), Center for Devices and Radiological Health (CDRH), is increasingly concerned with the number of imported medical devices that do not have sufficient entry data to allow the USFDA to make a prompt admissibility decision at the port of entry into the United States (US). The purpose of this letter is to provide specific recommendations to facilitate the import entry review process. These recommendations will directly impact your company’s ability to import medical devices, electronic product components, parts and finished product into the US.

The USFDA is attempting to help expedite the admissibility process for submissions that contain the correct Affirmations of Compliance (AofC) and other requested data. If appropriately submitted, this practice will increase the likelihood that your shipment may be processed based on import system screening and not held for further USFDA entry review. It is essential that the appropriate personnel associated with the import process (e.g., regulatory affairs, import personnel, brokers/filers, etc.) receive and understand this notification and that your company’s procedures are updated accordingly.

When an imported product arrives in the US, certain information must be provided/transmitted electronically to the United States Customs and Border Protection (CBP). If the product is or may be regulated by USFDA, CBP sends the import entry information to USFDA for verification to ensure that the product meets USFDA requirements. Without the proper information, USFDA may initiate a manual review of each line of your entry, which may lead to delays in its release to the importer/consignee.

Importers will need to work closely with their import personnel (brokers/filers) to verify that information submitted is correct to ensure the highest level of data quality. For the review of entries to be as expeditious as possible, consistent and accurate identifiers for firms and correct product codes for the product being imported must be submitted. Inaccurate and/or inconsistent data may lead to delays. Additionally, we encourage submission of AofC codes along with their appropriate qualifier. The submission of correct and accurate entry data and AofC codes will help expedite the entry review process and increase the likelihood that your shipment may be processed based on import system screening and that it is not held for further USFDA entry review.
The USFDA has developed new AofC codes and revised old AofC codes appropriate for use when transmitting entries of imported medical devices. In the following appendix you will find AofC codes with their associated descriptions and qualifiers for medical devices. Each entry line should contain an AofC code for:

- Device Foreign Manufacturer (DEV) or Device Foreign Exporter (DFE)
- Device Listing (LST)
- Device Initial Importer (DII)
- Premarket Application (PMA) (Can be a PMA, a Humanitarian Device Exemption (HDE), or a Product Development Protocol (PDP) number)
  OR a Premarket Notification Number (PMN)
  OR an Investigational Device Exemption (IDE)

Additional AofC codes can be provided as considered necessary. Use of these codes affirms that the product identified in a USFDA import entry line meets USFDA requirements specific to the product. While use of these AofC codes is voluntary, transmission will help expedite the entry review process and increase the likelihood that your shipment may be processed based on import system screening and is not held for further USFDA entry review.

Consistent and accurate supporting data also impacts radiation-emitting medical electronic products, such as medical lasers, diagnostic x-ray systems, etc. A second letter will be issued describing the import entry filing process for products subject to both the medical device and electronic product radiation regulations.

If you have any questions about the import entry review process for medical devices or any general questions regarding the entry screening process, please contact the CDRH Office of Compliance Import/Export Safety Staff at cdrhocimport@fda.hhs.gov. If you have questions related to a specific detained entry, you must first contact the Import Compliance Officer in your local USFDA District Office and reference the entry number for assistance.

Sincerely,

Steven Silverman
Director
Office of Compliance
Center for Devices and Radiological Health
Appendix - Medical Device Affirmations of Compliance (AofC)

AofC codes, their titles, and descriptions are provided below. Use of these codes affirms that the product identified in a USFDA line meets the requirements specific to the code. While use of AofC codes is voluntary, transmission will help expedite the entry review process. Each code listed should only be used once per entry line.

**CODE TITLE/DESCRIPTION**

*CPT Device Component*
This code should be used when importing a component of a device that requires further processing or inclusion into the finished device. This code is not to be used if the device component is classified by FDA as a finished device, e.g., wheelchair component. Whenever CPT is used, you should also provide the AofC DII.

*DEV Device Foreign Manufacturer Registration Number*
This code and qualifier should be the device registration number issued by CDRH for the firm manufacturing the product identified in the FDA line.

*DFE Device Foreign Exporter Registration Number*
The code and qualifier should be the device registration number issued by CDRH for the exporter who exports or offers for export to the United States (U.S.), a device manufactured or processed by another individual, partnership, corporation or association in a foreign country, as well as devices originally manufactured in the United States.

*DII Device Initial Importer Registration Number*
The code and qualifier should be the device registration number issued by CDRH for the importer who takes first title to devices imported into the U.S.

*IDE Investigational Device Exemption Number*
This code and qualifier should be the investigational device exemption number issued by CDRH for the product identified in the FDA line. An IDE number begins with the letter “G”.

*IFE Import for Export*
This code allows for importation of noncompliant articles (including drug and device components, food and color additives, and dietary supplements) under the new import for export provisions of the FD&C Act [801(d)(3)(a)]. The article must be incorporated, by the initial owner or consignee, (which can be someone other than the importer of record) into a product for export. The product must be exported from the United States by this initial owner or consignee in accordance with the provisions of Section 801(e) and 802 of the FD&C Act or 351(h) of the PHS Act. No qualifier is required but QUANTITY AND VALUE MUST BE TRANSMITTED when using this AofC.

*IRC Impact Resistance Lens Certification*
This code is used to certify that the filer/importer has on hand the test results or a certificate that shows that the product on the FDA line has met the standards for impact
resistance lens. See list of product codes in attachment, which require the use of this AofC.

LST Device Listing Number
The code and qualifier should be the device listing number issued by CDRH for the product identified in the FDA Line.

LWC (Electrode) Lead Wire or Patient Cable
This code is used when importing electrode lead wires, patient cables, or devices that use them. The affirmation means that (1) the device shipment does not contain any pre-wired electrodes, electrode lead wires, or patient (transducer) cables, or (2) any pre-wired electrodes, electrode lead wires or patient cables comply with 21 CFR 898, Performance Standard for Electrode Lead Wires and Patient Cables. See list of product codes in attachment, which require the use of this AofC.

MDL Model Number
The code and qualifier should be the manufacturer’s model number or catalog number for the product identified in the FDA line.

PMA Device Premarket Approval Number
This code and qualifier should be the Device Premarket Approval (PMA) number, product development protocol (PDP) number or Humanitarian Device Exemption (HDE) number issued by CDRH for the product identified in the FDA line. A PMA number begins with the letter ‘P’, a PDP number begins with the letter ‘D’, and a HDE begins with the letter ‘H’.

PMN Device Premarket Notification Number (510(k))
This code and qualifier should be the device premarket notification (510(k)) number issued by CDRH for the product identified in the FDA line. A PMN number begins with the letter ‘K’.

CODE - QUALIFIER EXAMPLES
Note: Should always be the DEV associated with the foreign manufacturer and not the US Specifications Developer.

DEV - 3003999999 or 9610123
DII - 3003999999 or 1021365
PMA - P001234
IDE - G01232
DFE - 3003999999 or 9710123
LST - E100100
PMN - K011234
MDL - 650 -182

ATTACHMENT - Product Codes for AofC IRC and LWC

List of product codes for AofC IRC:
(86H--OI) Spectacle, Magnifying
(86H--QG) Lens, Spectacle, Non-Custom (Prescription)
(86H--QY) Sunglasses (Non-Prescription Including Photosensitive)
(86N--JH) Lens, Spectacle (Prescription), for Reading Discomfort

List of product codes for AofC LWC:

73B--ZQ) Monitor, Breathing Frequency, 21 CFR 868.2375
(73F--LS) Monitor (Apnea Detector), Ventilatory Effort, 21 CFR 868.2375
(73K--OI) Stimulator, Nerve, Peripheral, Electric, 21 CFR 868.2775
(74D--PS) Electrocardiograph, 21 CFR 870.2340
(74D--QH) Cardiograph, Apex (Vibrocardiograph), 21 CFR 870.2310
(74D--RG) Transmitters And Receivers, Physiological Signal, Radiofrequency, 21 CFR 870.2910
(74D--RK) Dc-Defibrillator, High Energy, (Including Paddles), 21 CFR 870.5300
(74D--RO) Pacemaker, Cardiac, External Transcutaneous (Non-Invasive), 21 CFR 870.5550
(74D--RQ) Amplifier And Signal Conditioner, Transducer Signal, 21 CFR 870.2060
(74D--RT) Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm), 21 CFR 870.2300
(74D--RW) Adaptor, Lead Switching, Electrocardiograph, 21 CFR 870.2350
(74D--RX) Electrode, Electrocardiograph, 21 CFR 870.2360
(74D--SA) Cable, Transducer And Electrode, Patient, (Including Connector), 21 CFR 870.2900
(74D--SB) Plethysmograph, Impedance, 21 CFR 870.2770
(74D--SH) Recorder, Magnetic Tape, Medical, 21 CFR 870.2800
(74D--SI) Detector And Alarm, Arrhythmia, 21 CFR 870.1025
(74D--SJ) Alarm, Blood-Pressure, 21 CFR 870.1100
(74D--SK) Computer, Blood-Pressure, 21 CFR 870.1110
(74D--SR) Stimulator, Carotid Sinus Nerve, 21 CFR 870.3850
(74D--TA) Tester, Pacemaker Electrode Function, 21 CFR 870.3720
(74D--TD) Adaptor, Lead, Pacemaker, 21 CFR 870.3620

ATTACHMENT - Product Codes for IRC and LWC continued

(74D--TE) Pulse-Generator, Pacemaker, External, 21 CFR 870.3600
(74D--XG) Computer, Diagnostic, Pre-Programmed, Single-Function, 21 CFR 870.1435
(74D--XH) Transmitters And Receivers, Electrocardiograph, Telephone, 21 CFR 870.2920
(74D--XJ) Display, Cathode-Ray Tube, Medical, 21 CFR 870.2450
(74D--XK) Echocardiograph, 21 CFR 870.2330
(74D--XN) System, Measurement, Blood-Pressure, Non-Invasive, 21 CFR 870.1130
(74D--YC) Vectorcardiograph, 21 CFR 870.2400
(74J--OQ) Generator, Pulse, Pacemaker, External Programmable, 21 CFR 870.1750
(74K--RC) Tester, Electrode, Surface, Electrocardiographic, 21 CFR 870.2370
(74K--RE) Analyzer, Pacemaker Generator Function, Indirect, 21 CFR 870.3640
(74K--RG) Programmer, Pacemaker, 21 CFR 870.3700
(74L--DD) Dc-Defibrillator, Low-Energy, (Including Paddles), 21 CFR 870.5300
(74L--DF) Electrode, Pacemaker, Temporary, 21 CFR 870.3680
(74L--IW) Fibrillator, AC, 21 CFR 870.3680
(74L--OR) Resuscitator, Trans-Telephonic, 21 CFR 870.3680
(74L--OS) System, ECG Analysis, 21 CFR 870.2340
(74L--PA) System, Esophageal Pacing, 21 CFR 870.2340
(74L--PD) System, Pacing, Antitachycardia, 21 CFR 870.2340
(76L--YD) Stimulator, Electromagnetic Bone Growth for Dental Use, 21 CFR 870.2340
(78E--XQ) Cystometer, Electrical Recording, 21 CFR 876.1620
(78E--ZW) Percuaneous Leads For the Stimulator, electrical, implantable, for incontinence, 21 CFR No Regulation Class 3
(78F--AR) Unit, Electrosurgical, 21 CFR 876.4300
(78F--AS) Electrode, Electrosurgical, Active, Urological, 21 CFR 876.4300
(78F--BJ) Cord, Electric For Transurethral Surgical Instrument, 21 CFR 876.4300
(78F--DB) Plate, Patient, 21 CFR 876.4300
(78F--DI) Snare, Flexible, 21 CFR 876.4300
(78F--DJ) Snare, Rigid Self-Opening, 21 CFR 876.4300
(78F--DL) Wristlet, Patient Return, 21 CFR 876.4300
(78F--EH) Electrode, Flexible Suction Coagulator, 21 CFR 876.4300
(78F--FI) System, Alarm, Electrosurgical, 21 CFR 876.4300
(78F--FT) Electrode, pH, Stomach, 21 CFR 876.1400

**ATTACHMENT - Product Codes for IRC and LWC continued**

(78F--FX) System, Gastrointestinal Mobility, 21 CFR 876.1725
(78F--GW) Clamp, Electrical, 21 CFR 876.4300
(78F--HC) Adaptor To The Cord, For Transurethral Surgical Instrument, 21 CFR 876.4300
(78F--HZ) Desiccator, Transurethral, 21 CFR 876.4300
(78F--JD) Detector, Leak, Blood, 21 CFR 876.5820
(78F--LL) Thermometer, Electrical, Clinical, 21 CFR 880.2910
(78K--DO) Rongeur, Cystoscopic, Hot, 21 CFR 876.1500
(78K--GE) Forceps, Biopsy, Electric, 21 CFR 876.4300
(78K--LA) Monitor, Esophageal Mobility, and Tube, 21 CFR 876.1725
(78K--NS) Unit, Electrosurgical, Endoscopic (With or Without Accessories), 21 CFR 876.4300
(78K--NT) Feeding Tube Electrode, 21 CFR 876.5980
(78K--PI) Stimulator, Electrical for Incontinence (Non-Implantable), 21 CFR 876.5320
(78L--NL) Stimator, Electrical for Sperm Collection, 21 CFR 876.2040
(78L--NP) System, Hyperthermia, Extracorporeal, 21 CFR Unclassified
(78L--ST) Device, Erectile Dysfunction, 21 CFR 876.2040
(78M--II) System, Gallbladder Thermal Ablation, 21 CFR 876.2040
(78M--NW) Analyzer, Body Composition, 21 CFR 876.2040
(78M--YE) System, Electrogastrography (EGG), 21 CFR 876.1735
(78N--EZ) System, Imaging, Gastrointestinal, Wireless, Capsule, 21 CFR 876.1300
(78N--ZQ) Electrofluidigraph, 21 CFR Unclassified
(78O--AC) Plethysmograph, Air Displacement for Body Composition, 21 CFR 870.2770
(78O--BH) Monitor, Extracellular Fluid, Lymphedema, Extremity, 21 CFR 870.2770
(78O--DX) Autonomous Extracorporeal Blood Leak Detector/Alarm, 21 CFR 876.5820
(78O--EN) Hydration Status Monitor, Hemodialysis, 21 CFR Unclassified
(78O--KK) Body Composition Analyzer Health Assessment, 21 CFR Unclassified
(78O--MQ) Intravesical Electrode, 21 CFR No Regulation class 3
(78N--AX) Stimulator, Bladder, 21 CFR No Regulation class 3
(78F--DC) Resectoscope, Working Element, 21 CFR 876.1500
(78K--PN) Alarm, Conditioned Response Enuresis, 21 CFR 876.2040
(78N--LW) Electrode, Electrosurgical, Active, Urological, Reprocessed, 21 CFR 876.4300

ATTACHMENT - Product Codes for IRC and LWC continued
(78N--LV) Electrode, Flexible Suction Coagulator, Reprocessed, 21 CFR 876.4300
(78N--LU) Forceps, Biopsy, Electric, Reprocessed, 21 CFR 876.4300
(78N--WI) Kit, Electrode, Electrosurgical, 21 CFR 876.4300
(78N--LT) Snare, Flexible, Reprocessed, 21 CFR 876.4300
(78N--LR) Unit, Electrosurgical (with or without accessories), Reprocessed, 21 CFR 876.4300
(78F--FK) Lithotriptor, Electo-Hydraulic, 21 CFR 876.4480
(78N--AM) Stimulator, Peripheral Nerve, Non-Implanted, for Pelvic Floor Dysfunction, 21 CFR 876.5310
(79G--EI) Device, Electrosurgical, Cutting & Coagulation & Accessories, 21 CFR 878.4400
(79J--OS) Electrode, Electrosurgical, 21 CFR 878.4400
(84G--WF) Stimulator, Electrical, Evoked Response, 21 CFR 882.1870
(84G--WK) Conditioner, Signal, Physiological, 21 CFR 882.1845
(84G--WL) Amplifier, Physiological Signal, 21 CFR 882.1835
(84G--WN) Nystagmograph, 21 CFR 882.1460
(84G--WQ) Electroencephalograph, 21 CFR 882.1400
(84G--XC) Device, Electroconvulsive Therapy, 21 CFR 882.5940
(84G--XS) Monitor, Alpha, 21 CFR 882.1610
(84G--XY) Electrode, Cutaneous, 21 CFR 882.1320
(84G--XZ) Electrode, Needle, 21 CFR 882.1350
(84G--YC) Electrode, Cortical, 21 CFR 882.1310
(84G--YE) System, Telemetry, Physiological Signal, 21 CFR 882.1855
(84G--ZJ) Stimulator, Nerve, Transcutaneous, For Pain Relief, 21 CFR 5890
(84G--ZK) Electrode, Nasopharyngeal, 21 CFR 882.1340
(84G--ZL) Electrode, Depth, 21 CFR 882.1330
(84G--ZN) Rheoencephalograph, 21 CFR 882.1825
(84G--ZO) Device, Galvanic Skin Response Measurement, 21 CFR 882.1540
(84H--CB) Device, Aversive Conditioning, 21 CFR 882.5235
(84H--CC) Device, Biofeedback, 21 CFR 882.5050
(84H--CJ) Device, Skin Potential Measurement, 21 CFR 882.1560
(84J--XE) Device, Nerve Conduction Velocity Measurement, 21 CFR 882.1550
(84J--XK) Stimulator, Cranial Electrotherapy, 21 CFR 882.5800

**ATTACHMENT - Product Codes for IRC and LWC continued**
(84L--IH) Interferential Current Therapy, 21 CFR 882.5800
(84O--MC) Reduced Montage Standard Electroencephalograph, 21 CFR 882.1400
(84O--MA) Amplitude-Integrated Electroencephalograph, 21 CFR 1400
(84O--LV) Standard Polysomnograph with Electroencephalograph, 21 CFR 882.1400
(84O--LY) Magnetoencephalograph, 21 CFR 882.1400
(85H--II) Stimulator, Vaginal, Muscle, Powered, for Therapeutic Use, 21 CFR 884.5940
(86H--LL) Monitor, Eye Movement, 21 CFR 886.1510
(86H--LZ) Electrode, Corneal, 21 CFR 886.1220
(86H--MC) Monitor, Eye Movement, Diagnostic, 21 CFR 886.1510
(86H--QO) Unit, Cautery, Thermal, Ac-Powered, 21 CFR 886.4115
(86H--QR) Apparatus, Cautery, Radiofrequency, Ac-Powered, 21 CFR 886.4100
(86H--RO) Unit, Electrolysis, Ac-Powered, Ophthalmic, 21 CFR 886.4250
(87K--QX) Goniometer, Ac-Powered, 21 CFR 888.1500
(87L--BB) Dynamometer, Ac-Powered, 21 CFR 888.1240
(87L--OF) Non-Invasive Bone Growth Stimulator, 21 CFR 888.1240
(87L--WB) Functional Neuromuscular Stimulator For Scoliosis, 21 CFR 888.1240
(89E--GJ) Device, Iontophoresis, Other Uses, 21 CFR 890.5525
(89I--KD) Cable, Electrode, 21 CFR 890.1175
(89I--KN) Electromyograph, Diagnostic, 21 CFR 890.1375
(89I--KP) Chronaximeter, 21 CFR 890.1225
(89I--KT) Electrode, Needle, Diagnostic Electromyograph, 21 CFR 890.1385
(89I--MG) Stimulator, Ultrasound And Muscle, For Use In Applying Therapeutic Deep Heat, 21 CFR 890.5860
(89I--PF) Stimulator, Muscle, Powered, 21 CFR 890.5850
(89I--SB) Stimulator, Muscle, Diagnostic, 21 CFR 890.1850
(89K--TB) Device, Iontophoresis, Specific Uses, 21 CFR 890.5525
(89L--PQ) Stimulator, Ultrasound And Muscle, For Use Other Than Applying Therapeutic Deep, 21 CFR 890.5860
(89M--BN) Stimulator, Muscle, Powered, Invasive, 21 CFR 890.5860