9 Most Common Medical Device Entry Screening Errors

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While importers of medical devices may not see the benefit of each entry line being scored through the U.S. Food and Drug Administration's (FDA) Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system, this process has the potential to help speed up entry screening of their medical devices.

What is PREDICT?

PREDICT—the FDA's electronic screening tool for import operations—is designed to assist entry reviewers in targeting higher-risk shipments for examination. It works behind the scenes to screen all

lines of imported product electronically submitted to the FDA through the U.S. Customs Automated Commercial Environment (ACE) via the Automated Broker Interface (ABI) and then assigns a score to each line. A high score means a higher risk and a low score means a low risk. If your PREDICT score is lower, the product has the potential to clear faster.

Keep Your PREDICT Score Low

Importers should ensure they provide accurate and complete data, whether they file their own entries or have a Customs Broker file for them. If there is inaccurate or missing data, such as failing to provide a device listing number or entering inaccurate product codes, your PREDICT score goes up and is flagged as high-risk. This could result in delays for present and future shipments.

How to Avoid Common Errors

The FDA has provided a list of the most common errors for medical devices in fiscal year 2017. This should help importers and entry filers identify the types of criteria they might be missing or providing incorrectly.

When in doubt, importers should use reasonable care when providing entry data. Ensuring you supply the most accurate information will help keep your PREDICT score down and result in a low-risk rating, thus expedite the screening process.

Below are the FDA's most common entry errors for medical devices.

Most Common Entry Errors for Medical Devices in 2017

LST not transmitted
No listing number (LST) was transmitted for the entry. Verify that a listing number is required and provide one as applicable. There is no public website to search listing numbers because they are proprietary. Contact the listing entity to retrieve the number.

Could not find LST number
The listing number transmitted could not be found in FDA's database. Verify that the listing number provided is accurate and in the correct format.

Rgstrn not trnsmttd (DEV/DFE)
No registration number was transmitted for the foreign manufacturer (DEV) or foreign device exporter (DFE). Verify that a DEV, DDM or DFE is required and provide one as applicable.

Mnfctr has Country code = US
The listing number transmitted indicated that the manufacturer was a U.S. firm, but the manufacturer provided on the line is a foreign firm. Verify the correct LST was provided.

Product Code does not match
The product code transmitted for the entry did not match the product code on file for the listing number transmitted. Verify that the correct LST was provided and/or that the product code matches the LST.

Submission # does not match

The Pre-market notification or Premarket approval (PM#) transmitted for the entry did not match one of the numbers on file for the listing number transmitted. Verify that the PM# provided matches the product being introduced for import.

Firm name does not match
The firm name provided in the entry did not match the firm name on file for the listing number transmitted. Verify that the firm listed on the entry matches the firm used for the LST.

Registration does not match
The registration number provided in the entry did not match the registration number on file for the transmitted listing number. Verify the DEV provided matches the LST provided.

UNK is declared as IUC and the AofC REG supplied instead of DEV
When the Intended Use Code (IUC) is declared as unknown (UNK), inappropriate Affirmation of Compliance (AofC) qualifiers can be transmitted causing a lookup failure. Example: AofC provided was for Drug Registration (REG) not Device Manufacturer Registration (DEV) or Device Foreign Exporter Registration (DFE) as required for a device entry. Make sure when submitting a foreign device registration number that either DEV (manufacturer) or DFE (exporter) is used.

We understand the complexity of creating and maintaining a seamless compliance process. Contact Mohawk Global Trade Advisors to talk about how we can help you build a better Import Compliance Program.

FDA's Medical Device Common Entry Errors.

PREDICT Fact Sheet.

https://mohawkglobalta.com/9-common-medical-device-entry-screening-errors/