Catalog SOP: How to fix Medical Devices and Accessories Yanks

10/09/2024 1:25 pm CDT

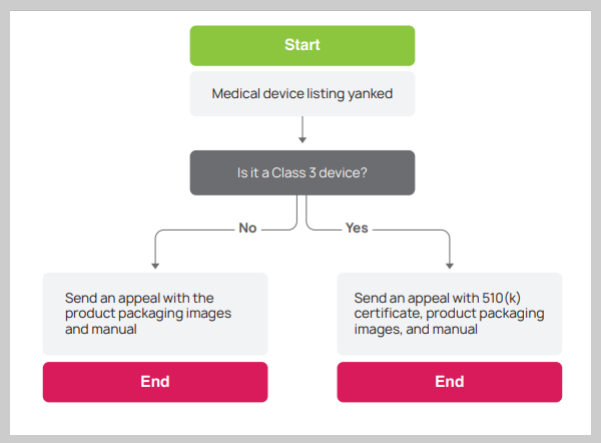
Who is this for: This SOP is for Amazon Sellers who are responsible for reinstating medical devices and accessories listings that have been yanked due to non-compliance with FDA regulations.

Objective: The objective of this SOP is to provide clear guidelines and instructions on how to reinstate medical devices and accessories listings on Amazon that have been removed due to non-compliance with FDA regulations. The document will help ensure that all listings comply with FDA regulations and that the products offered for sale on Amazon are safe and effective for human use.

Medical devices are regulated by the Food and Drug Administration (FDA), which is the U.S. federal agency that is responsible for ensuring that medical devices intended for human use are safe and effective. A medical device is an instrument, apparatus, machine, or related object used to diagnose, cure, treat, or prevent diseases in **people or animals.** Medical devices can also be used to change the structure or function of the body, such as, but not limited to, stimulating hair growth.[1]

To get more information about Medical Devices, see this **article**.

At a Glance



Restricted Product Policy Violation Warning/Details:

The violation details are located under "Reason" in Restricted Product Policy Violations in Account Health Performance. The details are very specific for each Yank reason. The following are just 2 out of many detail-page-removed reasons for Medical Devices and Accessories yanks:

- *This product has been identified as a microneedling skin roller or similar product that is considered a medical device due to either (1) the product's technical characteristics, as the product's needle length is greater than 0.3 mm, (2) the inclusion of medical marketing claims in the product details and/or images, or (3) a combination of both technical characteristics and marketing claims.*

- *This product has been identified as a pulse oximeter, which is a professional-use-only medical device. Per Amazon policy, professional-use-only medical devices may only be sold to appropriately licensed healthcare customers who have Amazon Business accounts. If you believe this determination was made in error and your product is not a professional-use-only medical device, please contact Seller or Vendor Support and (1) upload photos of all sides of the product packaging to the product detail page, (2) upload photos of the instructions for use included with the product to the product detail page, and (3) provide the 510(k) number issued by the U.S. Food & Drug Administration (FDA) for this product. If the name of the product provided on the product packaging, instructions for use, or ASIN detail page does not match the device name provided on the 510(k), please also provide, with the information noted above, (1) the device manufacturer's FDA establishment registration number OR owner/operator number, (2) the device name as it appears in the manufacturer's device listing, and (3) a purchase order, invoice OR letter (written in English) from the manufacturer confirming that the device was purchased from the manufacturer. For more information, please see our Medical Devices and Accessories Help Page (https://sellercentral.amazon.com/gp/help/external/help.html?itemID=200164650&language=en-US&ref=efph_200164650_cont_200164330) and the following FDA guidance: https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm https://www.fda.gov/MedicalDevices/Productsa*

How to Fix?

Document the changes/actions you will take.

The best way to fix a medical device Yank is by providing counterarguments against the Yank reason. You need to prove that Amazon claims aren't visible from the product's (a) **description,** (b) **instruction, and** (c) **label** or appeal that the product is eligible to use medical device claims.

Needful Things:

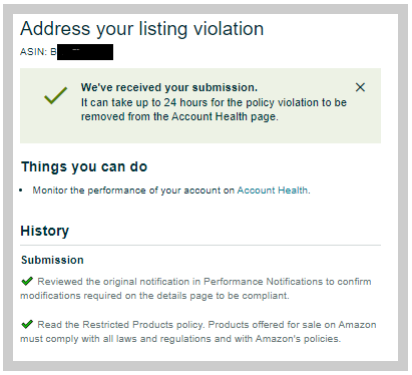
1. Photos of all sides of the product packaging ***just the packaging***).

2. Instructions manual for use included with the product (PDF format).

3. Screenshot of the FDA Establishment Registration & Device Listing and its link, if the product is FDA registered.
4. Manufacturer Invoice, if the product is a registered FDA medical device.
5. 510(k) number issued by the U.S. Food & Drug Administration (FDA) ***if the seller is participating in the Professional Health Care Program and if the yanked product is an FDA Medical Device 3.***

Actions:

1. **Identify your product -** Check your product's classification:
    a. **Non-medical device -** Go to step 2.
    b. **FDA medical devices 1 and 2 -** Get a screenshot of the FDA Establishment Registration & Device Listing link. You can obtain the information from your manufacturer.
    c. **FDA medical device 3 - Get a screenshot of the FDA registration of your product, its link, and the 510(k) certificate or number. You can obtain the information from your manufacturer.**
2. **Check the product description**
    a. **Non-medical device** - Remove any prohibited claims present from the product description (Title, Bullet Points, and Description), images, search terms keywords, and A+ content (description, images, and alt text keywords).
        i. Let's use the microneedling issue as an example. The reason states that the only allowed needle length without a certificate is less than 0.3 mm. Thus, make sure that there is no mention of 0.3 mm or higher length in the product description, images, search terms, and A+ content. Put the correct length of the needles as proof that the length is *shorter* than 0.3 mm, thus, a good counterargument against the yank reason. The same principle applies to all. It's best to do the changes through a ***feed file*** to obtain the ***batch ID***. Please follow the Download Category Listings Report **SOP**.
    b. **FDA medical devices 1, 2, and 3 -** Ensure that the product description, images, search terms, and A+ content are in harmony with the description in the FDA registration information. It's best to do the changes through a ***feed file*** to obtain the ***batch ID***. Please follow the Download Category Listings Report **SOP**.
3. **Product Documents**
    a. **Non-medical device**
        i. **Product packaging images -** You may need to take product packaging images (all sides). Amazon may ask for the images for them to further check the label if it's compliant with the Medical Devices and Accessories policy.
        ii. **Product instructions manual -** You may need to provide the instructions manual if Amazon asks for it. If your product has no instructions manual, tell Amazon and focus on the product label's content.
    b. **FDA medical devices 1 and 2**
        i. **FDA Establishment Registration & Device Listing and its link -** Take a screenshot of your product information from the FDA website. You can get the FDA information from your manufacturer. You can look up the Establishment Registration & Device Listing here.
        ii. **Product packaging images -** You'll need to provide the product packaging images for Amazon to see if it has complete information about the product. T**ake product packaging images (all sides).**
        iii. **Product instructions manual -** You'll need to provide the product instructions manual (if any) for Amazon to see if it's in the harmony with the registered product information under FDA.
        iv. **Manufacturer Invoice -** You'll need to provide the manufacturer invoice of your product. The manufacturer invoice and the FDA Registered Establishment Name information should match. It's also proof that you're an eligible seller of the product.
    c. **FDA medical device 3**
        i. **The same documents showed above plus;**
        ii. **510(k) Certificate -** 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device. You can obtain this certificate from your manufacturer
4. **Appeal -** If you're confident that everything is set, go to Performance > Account Health > Restricted Product Policy Violations > Look for the ASIN > Appeal > Check the 2 boxes and Submit. Wait 24 hours before the listing gets reinstated.



What if the listing remained yanked?

1. Send a ticket. Follow this pathway Help > Get Support > Selling on Amazon > Or, browse for your issue in the menu > Products, Listings, or Inventory > Inventory file upload issue. Here's **how to file a ticket**.
2. Title/Reason: **"US - Restricted Products - Appeal - ASIN: B0xx"**
3. Body (the following is just an example, please don't copy but tweak it depending on the actions you took).

Non-medical device template:

Greetings,

ASIN B0xxxxxxxx was yanked because it was classified/falsely classified as a product claiming to be a microneedling skin roller.

We want to appeal that this item is a toiletry travel bag and it doesn't have any microneedling terms in its description or keywords. Also, we have uploaded the instructions manual of this product in Product Documents. Please see that the specifications show that the length of the needles is 0.22mm shorter than 0.3 mm which is against your medical devices policy.

I have attached photos of all sides of the packaging for you to review.

Please reinstate the listing. Send this to the internal team for further review and reinstatement.

Medical device template:

Greetings Amazon,

ASIN B0xxxxxxxx was yanked because it was classified/falsely classified as a product claiming to be a microneedling skin roller.

We want to dispute that ASIN B0xx is an approved [medical device type] by FDA.

Here is the important information about ASIN B0xx.

Manufacturer: [Insert the Manufacturer's Business Name]

FDA Regulation Number: 878.4040

FDA Establishment Registration & Device Listing Link:

[Insert the FDA registration and device link]

FDA Regulation Link:

[Insert the FDA regulation link]

We are an authorized seller of [Manufacturer name] [medical device type]. We have attached the sales contract invoice of the manufacturer.

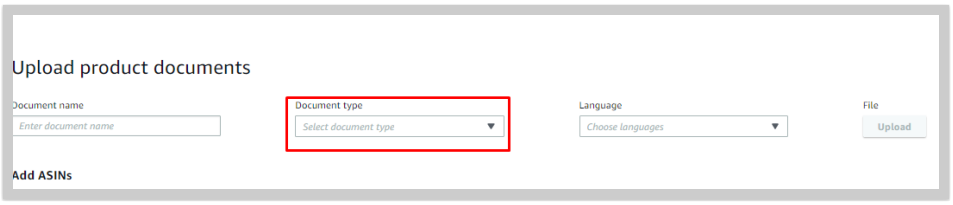
We have also attached the product packaging images and the product instructions manual for you to review.

Please send this to the internal team for further review and reinstatement.

4. Get the case ID and monitor the updates.

Preventive Measures

1. The product instructions manual should be uploaded in **Product Documents**. Please follow this pathway Inventory > Manage Product Documents > Upload New Document > Fill out the necessary fields > for Document type, select either ***User Guide, User Manual, or Application Guide.***



Useful Tool:

FDA Establishment Registration & Device Listing

Reference:

1. https://sellercentral.amazon.com/help/hub/reference/G200164650 ↑