

Listing Combination Products in FURLS/DRLM

Regulatory Policy and Systems Branch
Division of Risk Management Operations
Office of Compliance
Center for Devices and Radiological
Health
May 2012



Create Listing - Exempt Combination Product

- Screen shots
 - What industry sees when create listing for an exempt combination product
 - How to create the listing via the “Create Listing for Medical Devices” link found on DRLM Main Menu
- Listings created through other menu selections require the same input

Steps: Create Listing – Exempt Combination Product

- Step 1: Log into FURLS/DRLM
- Step 2: Click on “Device Registration and Listing”
- Step 3: Click on “Continue” on page with red text

Step 4: Click on “Create Listings for Medical Devices” link



 [Annual Registration](#)
(Annual Review of Device Registration and Listing Information)

 [View Your Registration and Listing Information](#)

 [Change Registration Information for a Facility](#)

 [Cancel, Deactivate, or Reactivate a Facility Registration](#)

 [Change the Official Correspondent for a Facility](#)

 [Register a New Medical Device Facility](#)

 [Create Listings for Medical Devices](#)

 [Change, Cancel, or Reactivate Listings](#)

 [Transfer Ownership of Devices or Facilities](#)

Step 5: For exempt, leave Premarket Submission Number blank and check box if combination product

DRLM
Device Registration & Listing Module

CREATE A NEW DEVICE LISTING
Enter Product Number Get Help ?

Important Notice: If you are required to pay an annual registration user fee, you must visit the [FDA User Fee website](#) and pay the fee prior to registering your facility. To determine if you need to pay the fee, please [click here](#).

For the product you are listing, enter one of the following:

- Premarket Notification (510(k)) number
- Premarket Application (PMA) number
- Product Development Protocol (PDP) number
- Humanitarian Device Exemption (HDE) number
- Investigational New Drug (IND) number
- New Drug Application (NDA) number

If you believe the product you are listing falls under enforcement discretion or preamendment, please contact the CDRH Registration and Listing Helpdesk at regist@cdRH.fda.gov.

If your device is exempt from FDA premarket notification requirements, leave the box empty.

If the product is a combination product, please check the Combination Product checkbox and then click "Continue".

Enter the Premarket Submission Number:

Click this box if your device is part of a combination product that includes a drug or biologic

< CANCEL - RETURN to MAIN MENU **> CONTINUE**

Step 6: Answer Question

DRLM
Device Registration & Listing Module

 **FDA** FURLS HOME
DRLM HOME


Create a New Device Listing
Create a New Exempt Listing Get Help ?

Are all of the facilities manufacturing this product located in the United States?

YES NO

Step 7: Answer Dental Laboratory Question (if you answered No on the previous screen)

DRLM
Device Registration & Listing Module

 **FDA** FURLS HOME
DRLM HOME

Create a New Device Listing

Dental Laboratory Question Get Help ?

Is this a product exported to the United States from a dental laboratory located outside of the United States?

YES NO

Step 8: Enter string or product in text box, then click radio button next to product code

DRLM
Device Registration & Listing Module

FDA FURLS HOME
DRLM HOME

Create a New Device Listing [Get Help ?](#)

- Select Product Code(s)

Shorten your search by using the filter option. Type a word or words describing the device and click Filter. A list of product codes and names will appear below. If you already know the correct product code, type the product code in the box and click Filter. Once you have selected a product code and identified the type(s) of combination product(s) this device is a part of, click Continue.

Enter the Product Code or a word or words describing the device:

Displaying Page 1 of 1

	Specialty	Code	Device/Product Name	Class	Submission Required
<input checked="" type="radio"/>	GENERAL AND PLASTIC SURGERY	GDX	SCALPEL, ONE-PIECE	1	510(k) exempt
<input type="radio"/>	GENERAL AND PLASTIC SURGERY	GDZ	HANDLE, SCALPEL	1	510(k) exempt

Step 9: Check box that describes combination product

<input type="radio"/>	OBSTETRICS AND GYNECOLOGY	HQP	ELECTRODE, CIRCULAR (SPIRAL), SCALP AND APPLICATOR	2	510(k)
<input type="radio"/>	OBSTETRICS AND GYNECOLOGY	HQ	Electrode, clip, fetal scalp (and applicator)	3	pma
<input type="radio"/>	NEUROLOGY	HBO	CLIP, SCALP	2	510(k)
<input type="radio"/>	GENERAL AND PLASTIC SURGERY	NLQ	SCALPEL, ULTRASONIC, REPROCESSED	U	510(k)

Please make a selection or selections below that most closely describe your combination product:

- CONVENIENCE KIT OR CO-PACKAGE
- PREFILLED DRUG DELIVERY DEVICE/SYSTEM (SYRINGE, PATCH, ETC.)
- PREFILLED BIOLOGIC DELIVERY DEVICE/SYSTEM (SYRINGE, PATCH, ETC.)
- DEVICE COATED/IMPREGNATED/OTHERWISE COMBINED DRUG
- DEVICE COATED OR OTHERWISE COMBINED WITH BIOLOGIC
- DRUG-BIOLOGIC COMBINATION
- SEPARATE PRODUCTS REQUIRING CROSS LABELING
- POSSIBLE COMBINATION BASED ON CROSS LABELING OF SEPARATE PRODUCTS
- OTHER TYPE OF PART 3 COMBINATION PRODUCT (E.G., DRUG-DEVICE/BIOLOGIC PRODUCT)

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> CONTINUE

Types of Combination Products

- Convenience Kit Or Co-Package
- Prefilled Drug Delivery Device/System (Syringe, Patch, Etc.)
- Prefilled Biologic Delivery Device/System (Syringe, patch, etc.)
- Device Coated/Impregnated/Otherwise Combined Drug
- Device Coated Or Otherwise Combined With Biologic
- Drug/Biologic Combination
- Separate Products Requiring Cross Labeling
- Possible Combination Based On Cross Labeling Of Separate Products
- Other Type Of Part 3 Combination Product (e.g., Drug/Device/Biologic Product)

Types of Combination Product (Cont'd)

- Descriptions for type of combination product can be found at:
<http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm>

Step 10: Select Facility

DRLM
Device Registration & Listing Module


 **FDA** FURLS HOME
DRLM HOME

Create a New Device Listing
Select Facilities for the New Device Listing [Get Help ?](#)

<input type="checkbox"/>	Name and Address	Registration Number
<input checked="" type="checkbox"/>	FDA 10903 New Hampshire Ave Rm 2211 , Silver Spring , Maryland , 20903 , UNITED STATES	Registration Number Not Yet Assigned
<input type="checkbox"/>	MAXILON LABORATORIES, INC. 105 STATE RT. 101A, UNIT B , AMHERST , New Hampshire , 03031 , UNITED STATES	1225686
	Plurinational?	

Step 11: Select Activity

DRLM
Device Registration & Listing Module

 **FDA** FURLS HOME
DRLM HOME

Create a New Device Listing
Select Activities for the New Device Listing Get Help ?

Facility: *FDA - Silver Spring, Maryland, UNITED STATES*

Select all activities related to this device that are performed at your facility.

- Manufacture Medical Device*
- Develop Specifications But Do Not Manufacture At This Facility*
- Manufacture and Distribute Medical Device for Another Party (Contract Manufacturer)*
- Sterilize and Distribute Medical Device for Another Party (Contract Sterilizer)*
- Reprocess Single-Use Device*
- Repack or Relabel Medical Device
- Remanufacture Medical Device
- Export Device to the United States But Perform No Other Operation on Device
- Manufacture Device in the United States for Export Only*

*Requires payment of annual registration user fee.

Important Notice: If you are required to pay an annual registration user fee, you must visit the [FDA User Fee website](#) and pay the fee prior to registering your facility. To determine if you need to pay the fee, please [click here](#).

Step 12: Add Proprietary Name

Enter any proprietary or brand names that your product is distributed under, then click Continue.

Proprietary Name(s):

Scalpel One

< Remove

✓

^ Add Proprietary Name

- Click [here](#) to download a sample spreadsheet in the correct format.
- Enter the proprietary names into the sample Excel spreadsheet and save or into an Excel spreadsheet formatted exactly as shown in the sample
- Be sure to save your spreadsheet to a place you will remember on your local drive
- Click "Browse" to go to the saved spreadsheet, then click "Upload"

Browse...

> UPLOAD

< BACK

< CANCEL - RETURN to MAIN MENU

> CONTINUE



Adding Proprietary Names

- Firms can now use an excel spreadsheet to upload proprietary names for device(s)
- Sample format is read-only
- Need to download the spreadsheet to add proprietary names to it
- Save on local or hard drive
- Click Browse and Upload into FURLS/DRLM

Download Excel Template

Enter any proprietary or brand names that your product is distributed under, then click Continue.

Proprietary Name(s):

Scalpel One

< Remove

^ Add Proprietary Name

You can also upload an Excel spreadsheet with the proprietary names for your device as follows:

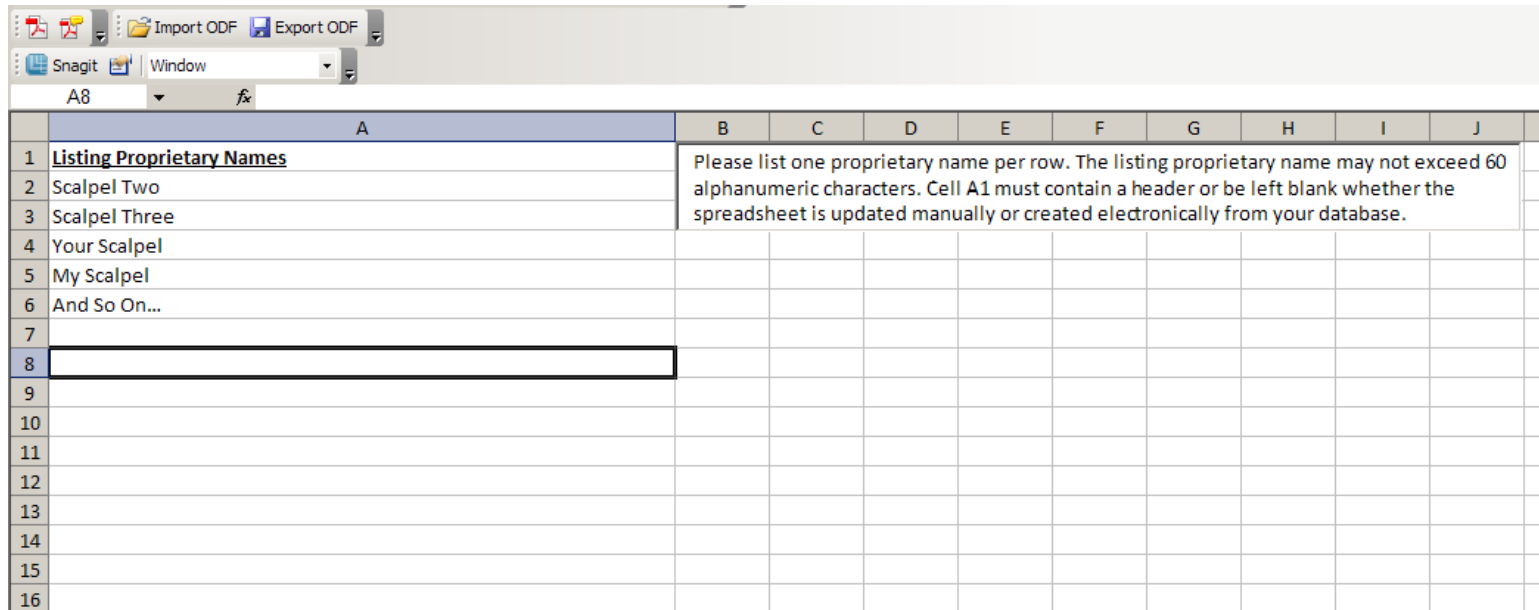
- Click [here](#) to download a sample spreadsheet in the correct format.
- Enter the proprietary names into the sample Excel spreadsheet and save or into an Excel spreadsheet formatted exactly as shown in the sample
- Be sure to save your spreadsheet to a place you will remember on your local drive
- Click "Browse" to go to the saved spreadsheet, then click "Upload"

Browse...

> UPLOAD

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Adding Proprietary Names: Sample Format



	A	B	C	D	E	F	G	H	I	J
1	Listing Proprietary Names	Please list one proprietary name per row. The listing proprietary name may not exceed 60 alphanumeric characters. Cell A1 must contain a header or be left blank whether the spreadsheet is updated manually or created electronically from your database.								
2	Scalpel Two									
3	Scalpel Three									
4	Your Scalpel									
5	My Scalpel									
6	And So On...									
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										

Save to a folder/location you will remember

Upload Excel File With Names

Enter any proprietary or brand names that your product is distributed under, then click Continue.

Proprietary Name(s):

Scalpel One

< Remove

^ Add Proprietary Name

You can also upload an Excel spreadsheet with the proprietary names for your device as follows:

- Click [here](#) to download a sample spreadsheet in the correct format.
- Enter the proprietary names into the sample Excel spreadsheet and save or into an Excel spreadsheet formatted exactly as shown in the sample
- Be sure to save your spreadsheet to a place you will remember on your local drive
 - Click "Browse" to go to the saved spreadsheet, then click "Upload"

C:\Documents and Settings\drg\My Documents\Downloads>Listir

> UPLOAD

< BACK < CANCEL - RETURN to MAIN MENU > CONTINUE

Upload Excel File With Names - Result

Enter any proprietary or brand names that your product is distributed under, then click Continue.

Proprietary Name(s):

- Scalpel One
- Scalpel Two
- Scalpel Three
- Your Scalpel
- My Scalpel

< Remove

▲ Add Proprietary Name

You can also upload an Excel spreadsheet with the proprietary names for your device as follows:

- Click [here](#) to download a sample spreadsheet in the correct format.
- Enter the proprietary names into the sample Excel spreadsheet and save or into an Excel spreadsheet formatted exactly as shown in the sample
- Be sure to save your spreadsheet to a place you will remember on your local drive
- Click "Browse" to go to the saved spreadsheet, then click "Upload"

Browse...

> UPLOAD

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Adding Proprietary names: Sample Format (cont'd.)

- Firms can generate their own file for each listing as long as it is in the same format
- Format is simple - all names must be in Column A and cell A1 must either be a header or blank.
- Proprietary names up to 60 characters now
- Working on increasing proprietary name to allow 120 characters

Step 13: Review Listing

Review the listing you selected. If all of the information is correct, click Finish.

Submission Type	Product Code(s)	Device Name(s)	Proprietary Names	Facility Registration Number - Activities
Exempt	00X	SCALPEL, ONE-PIECE	Scalpel One Scalpel Two Scalpel Three Your Scalpel My Scalpel And So On...	Registration Number: Not Yet Assigned (Repackager/Relabeler)

> EDIT

Certification Statement


 By clicking the Finish button I certify that the registration and listing information for this medical device facility as shown on this page is true. I understand that the submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C 1001.

If any of the facilities included on this listing have not previously paid the annual registration fee for the current fiscal year and are now required to pay the fee, you will be prompted to enter your Payment Identification Number (PIN) and Payment Confirmation Number (PCN) for each facility that must pay after you click Submit. If you are required to pay the fee and have not yet purchased your PIN/PCN, you must visit the [FDA User Fee website](#) and pay the annual registration fee.

< CANCEL - RETURN TO MAIN MENU > FINISH

Step 14: Listing Confirmation

DRLM
Device Registration & Listing Module

 **FDA** FURLS HOME
DRLM HOME

Confirmation - Create a New Device Listing Get Help ?

Be sure to print a copy of this page to maintain a record of the details about this new listing.

Note: If this listing is for product(s) that will be exported to the United States from a Country/Area outside the U.S., be sure to reference the listing number and your registration number on all shipping invoices.

Listing Number	Submission Type	Product Code(s)	Device Name(s)	Proprietary Names	Facility Registration Number - Activities
D128829	Exempt	GDX	SCALPEL, ONE-PIECE	Scalpel One Scalpel Two Scalpel Three Your Scalpel My Scalpel And So On...	Registration Number: Not Yet Assigned. [Repackager/Relabeler]

[< RETURN TO MAIN MENU](#) [> ADD NEW LISTING](#)



Create Listing – Non-exempt Combination Product

- Screen shots show what industry sees when create listing for an exempt combination product
- Screen shots show how to create the listing via the “Create Listing for Medical Devices” link found on DRLM Main Menu



Steps: Create Listing – Non-Exempt Combination Product

- Step 1: Log into FURLS/DRLM
- Step 2: Click on “Device Registration and Listing”
- Step 3: Click on “Continue” on page with red text

Step 4: Enter Premarket Submission Number

DRLM
Device Registration & Listing Module

CREATE A NEW DEVICE LISTING
Enter Product Number Get Help ?

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For the product you are listing, enter one of the following:

- Premarket Notification (510(k)) number
- Premarket Application (PMA) number
- Product Development Protocol (PDP) number
- Humanitarian Device Exemption (HDE) number
- Investigational New Drug (IND) number
- New Drug Application (NDA) number

If you believe the product you are listing falls under enforcement discretion or preamendment, please contact the CDRH Registration and Listing Helpdesk at regist@cdrh.fda.gov.

If your device is exempt from FDA premarket notification requirements, leave the box empty.

If the product is a combination product, please check the Combination Product checkbox and then click "Continue".

Enter the Premarket Submission Number: ✓


Click this box if your device is part of a combination product that includes a drug or biologic ✓

[< CANCEL - RETURN to MAIN MENU](#) [> CONTINUE](#)

If device is combination product in premarket database, firm can go to the next screen where they identify the type of combination product

Step 5: Check type of combination product

DRLM
Device Registration & Listing Module

 **FDA** FURLS HOME
DRLM HOME

Create a New Device Listing Get Help ?

Product codes for the non-exempt device K931333:

Medical Specialty	Product Code	Device/Product Name	Class
ORTHOPEDIC	LPH	PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, POROUS UNCEMENTED	2

Please make a selection or selections below that most closely describe your combination product:

- CONVENIENCE KIT OR CO-PACKAGE
- PREFILLED DRUG DELIVERY DEVICE/SYSTEM (SYRINGE, PATCH, ETC.)
- PREFILLED BIOLOGIC DELIVERY DEVICE/SYSTEM (SYRINGE, PATCH, ETC.)
- DEVICE COATED/IMPREGNATED/OTHERWISE COMBINED DRUG
- DEVICE COATED OR OTHERWISE COMBINED WITH BIOLOGIC
- DRUG/BIOLOGIC COMBINATION
- SEPARATE PRODUCTS REQUIRING CROSS LABELING
- POSSIBLE COMBINATION BASED ON CROSS LABELING OF SEPARATE PRODUCTS
- OTHER TYPE OF PART 3 COMBINATION PRODUCT (E.G., DRUG/DEVICE/BIOLOGIC PRODUCT)

Step 6: Select Facility

DRLM
Device Registration & Listing Module


 **FDA** FURLS HOME
DRLM HOME

Create a New Device Listing
Select Facilities for the New Device Listing [Get Help ?](#)

<input type="checkbox"/>	Name and Address	Registration Number
<input checked="" type="checkbox"/>	FDA 10903 New Hampshire Ave Rm 2211 , Silver Spring , Maryland , 20903 , UNITED STATES	Registration Number Not Yet Assigned
<input type="checkbox"/>	MAXILON LABORATORIES, INC. 105 STATE RT. 101A, UNIT B , AMHERST , New Hampshire , 03031 , UNITED STATES	1225686
	Plurinational?	

Step 7: Select Activity

DRLM
Device Registration & Listing Module

 **FDA** FURLS HOME
DRLM HOME

Create a New Device Listing Get Help ?

Select Activities for the New Device Listing

Facility: FDA - Silver Spring, Maryland, UNITED STATES

Select all activities related to this device that are performed at your facility.

- Manufacture Medical Device*
- Develop Specifications But Do Not Manufacture At This Facility*
- Manufacture and Distribute Medical Device for Another Party (Contract Manufacturer)*
- Sterilize and Distribute Medical Device for Another Party (Contract Sterilizer)*
- Reprocess Single-Use Device*
- Repack or Relabel Medical Device
- Remanufacture Medical Device
- Export Device to the United States But Perform No Other Operation on Device
- Manufacture Device in the United States for Export Only*

*Requires payment of annual registration user fee.

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Step 8: Add Proprietary Name

Proprietary Names

Enter any proprietary or brand names that your product is distributed under, then click Continue.

Proprietary Name(s):

Hip Model 4217

< Remove

✓

^ Add Proprietary Name

You can also upload an Excel spreadsheet with the proprietary names for your device as follows.

- Click [here](#) to download a sample spreadsheet in the correct format.
- Enter the proprietary names into the sample Excel spreadsheet and save or into an Excel spreadsheet formatted exactly as shown in the sample
- Be sure to save your spreadsheet to a place you will remember on your local drive
- Click "Browse" to go to the saved spreadsheet, then click "Upload"

Browse...

> UPLOAD

< BACK < CANCEL - RETURN to MAIN MENU > CONTINUE


Step 9: Review Listing

Review the listing you selected. If all of the information is correct, click Finish.

Premarket Submission Number	Product Code(s)	Device Name(s)	Proprietary Names	Facility Registration Number - Activities
K931333	LPH	PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, POROUS UNCEMENTED	Hip Model 4217	Registration Number: Not Yet Assigned. [Repackager/Relabeler]

> EDIT

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< CANCEL - RETURN TO MAIN MENU > FINISH

Step 10: Listing Confirmation

Confirmation - Create a New Device Listing

Get Help 

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Note: If this listing is for product(s) that will be exported to the United States from a Country/Area outside the U.S., be sure to reference the listing number and your registration number on all shipping invoices.

Listing Number	Premarket Submission Number	Product Code(s)	Device Name(s)	Proprietary Names	Facility Registration Number - Activities
D128628	K931333	LPH	PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, POROUS UNCEMENTED	Prosthesis	Registration Number: Not Yet Assigned. [Repackager/Relabeler]

[◀ RETURN TO MAIN MENU](#)

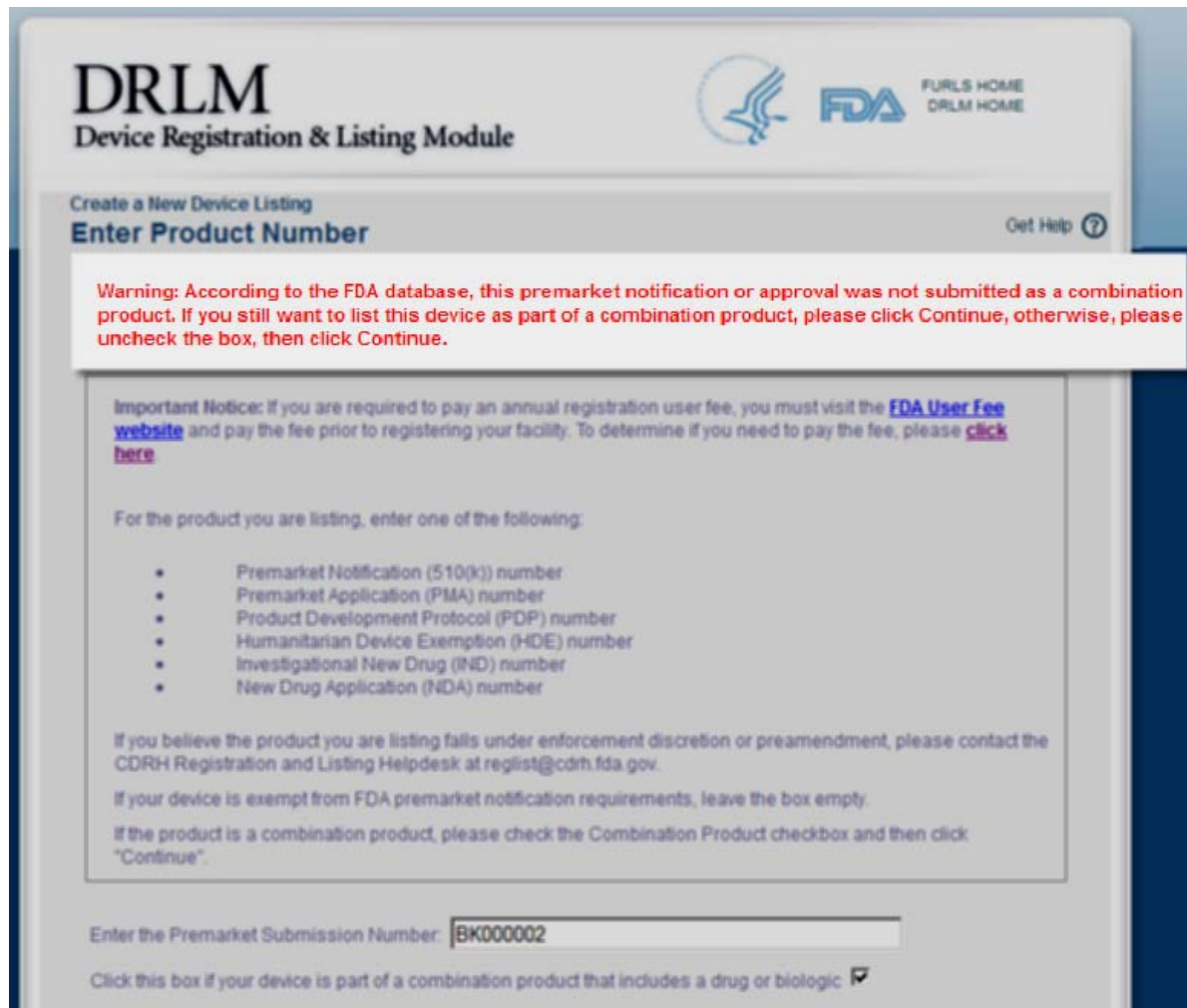
[▶ ADD NEW LISTING](#)




Combination Product Rules

- If device is not a combination product in premarket database, an error message displays telling firm that it is not.
- Firm can go ahead and list and identify the type of combo product.

Error Message



DRLM
Device Registration & Listing Module

 **FDA** FURLS HOME
DRLM HOME

Create a New Device Listing Get Help ?

Enter Product Number

Warning: According to the FDA database, this premarket notification or approval was not submitted as a combination product. If you still want to list this device as part of a combination product, please click Continue, otherwise, please uncheck the box, then click Continue.

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- New Drug Application (NDA) number

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If the product is a combination product, please check the Combination Product checkbox and then click "Continue".

Enter the Premarket Submission Number:

Click this box if your device is part of a combination product that includes a drug or biologic



Questions about Listing Combination Products

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