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

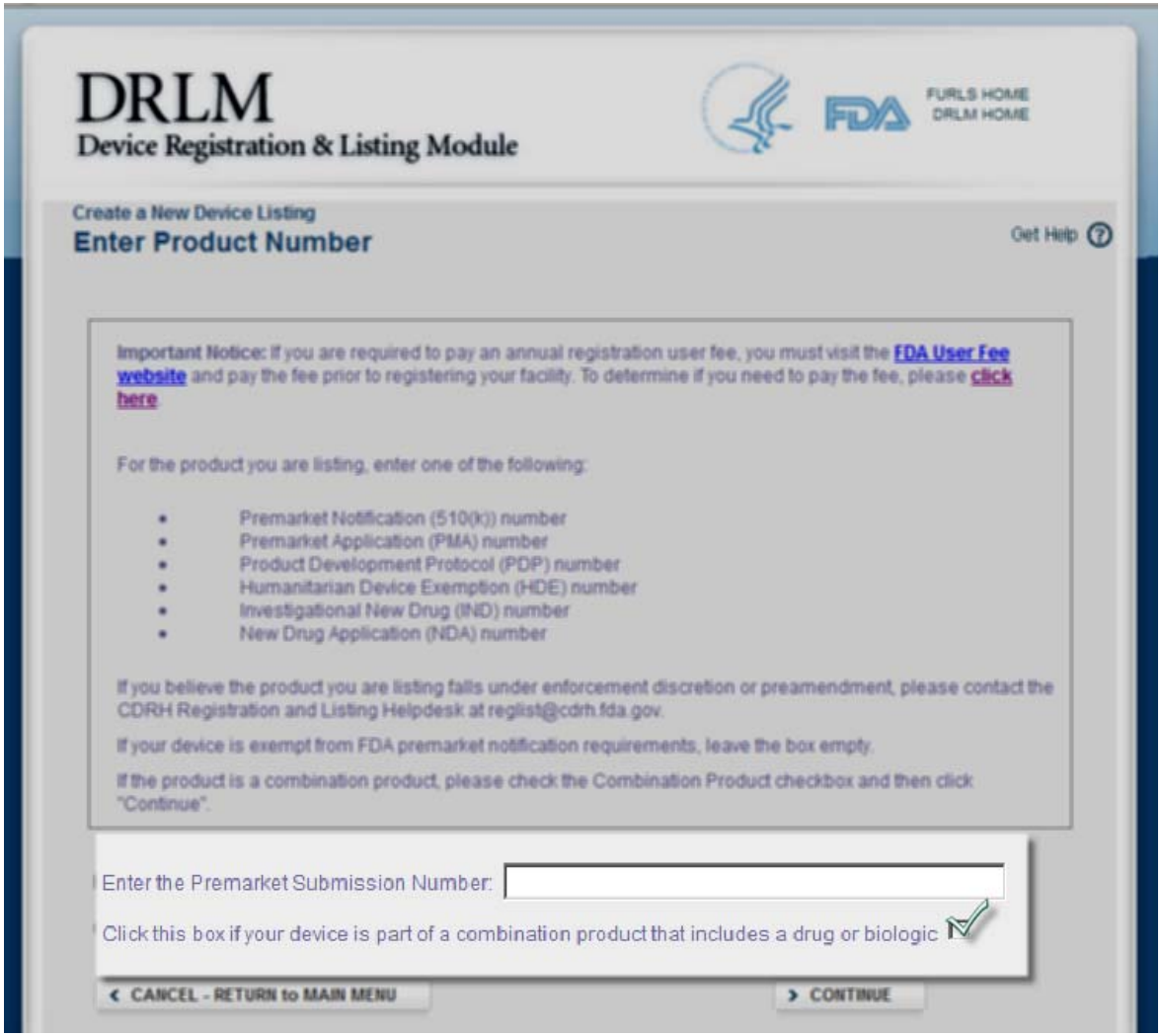
- Screen shots
  - What industry sees when create listing for an exempt combination product
  - How to create the listing via the "Create Listing for Medical Devices" link found on DRLM Main Menu
- Listings created through other menu selections require the same input

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

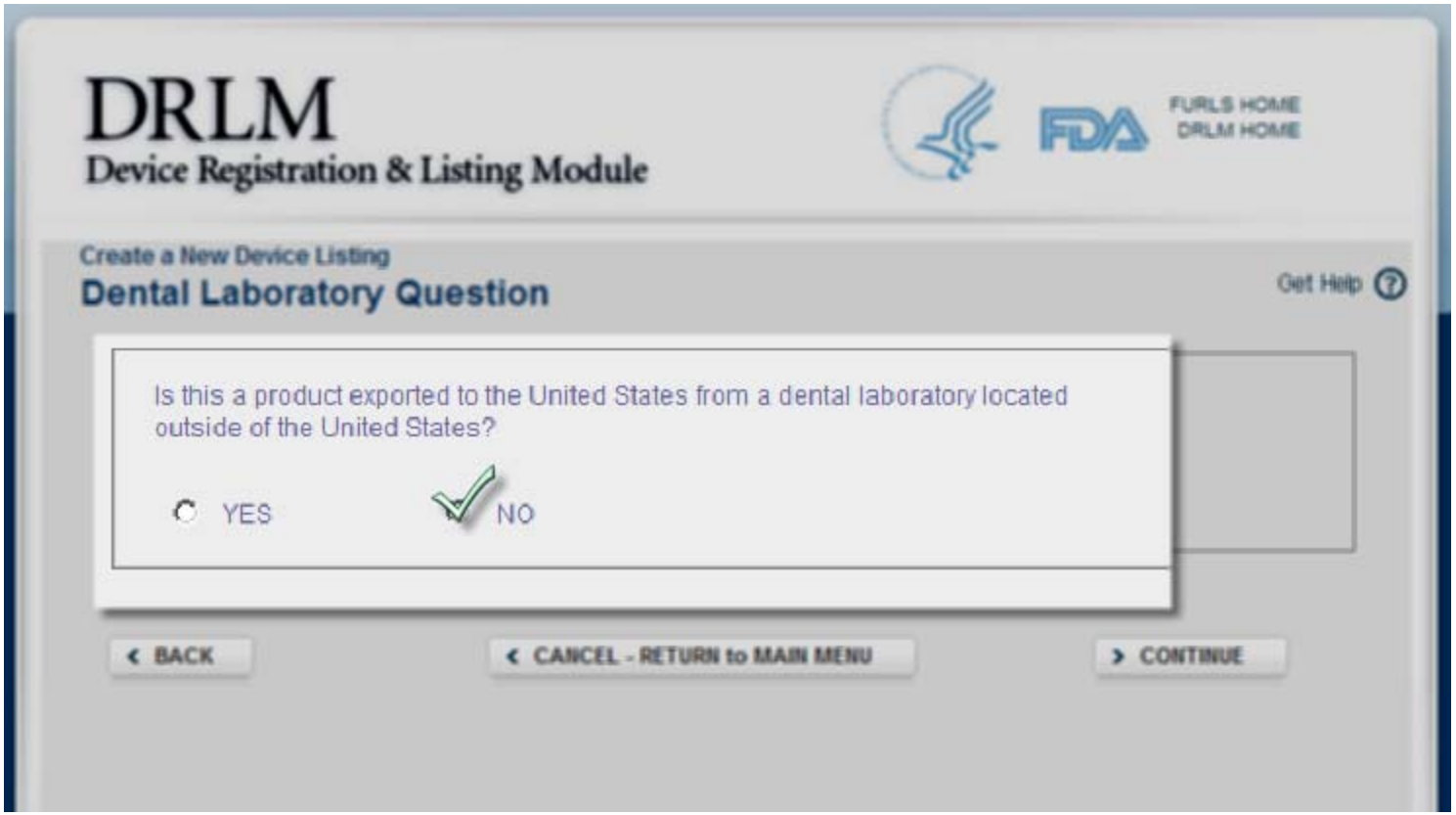
Step 4: Click on “Create Listings for Medical Devices” link

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



Step 6: Answer Question

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



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

Step 9: Check box that describes combination product

○	OBSTETRICS AND GYNECOLOGY	HGP	ELECTRODE, CIRCULAR (SPIRAL), SCALP AND APPLICATOR	2	510(k)
○	OBSTETRICS AND GYNECOLOGY	HIQ	Electrode, clip, fetal scalp (and applicator)	3	pma
○	NEUROLOGY	HBO	CLIP, SCALP	2	510(k)
○	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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Types of Combination Products

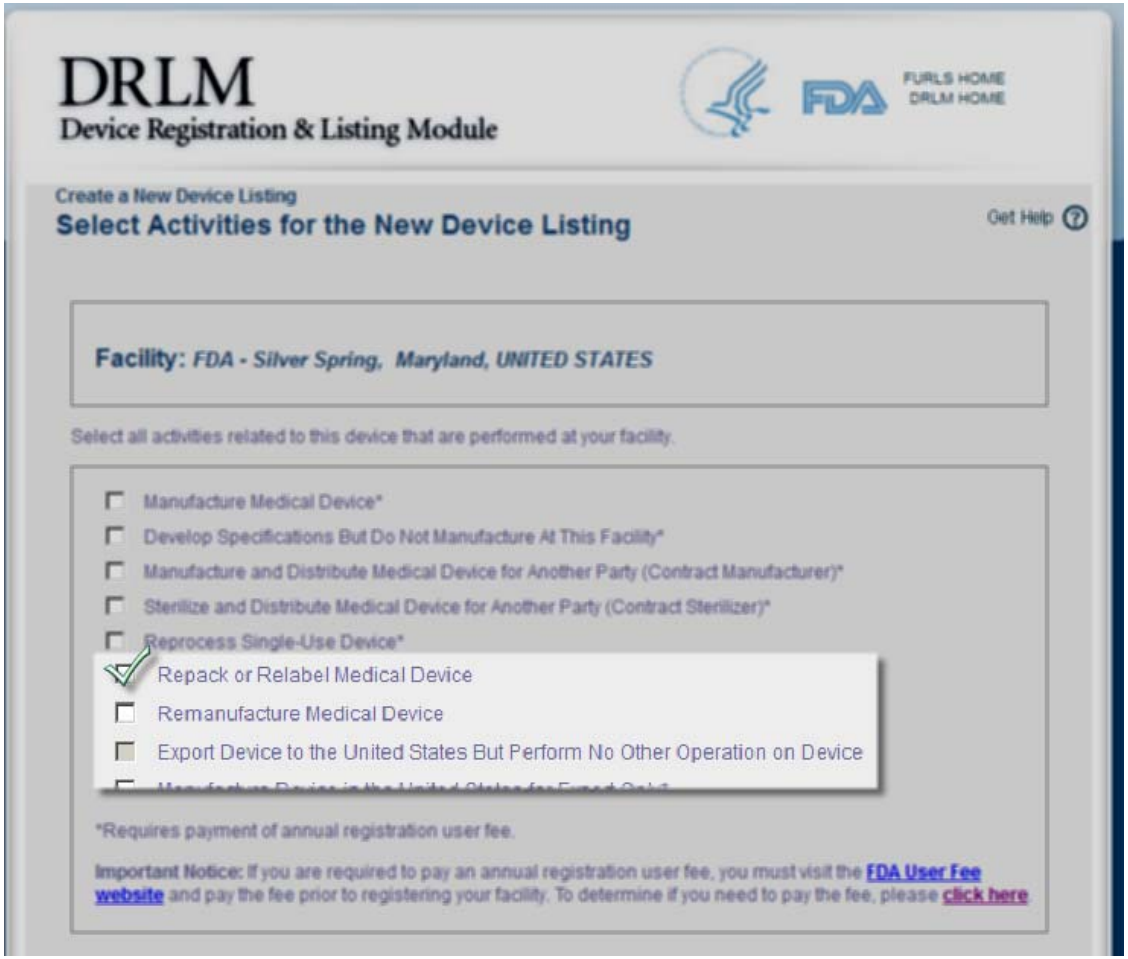
- Convenience Kit Or Co-Package
- Prefilled Drug Delivery Device/System (Syringe, Patch, Etc.)
- Prefilled Biologic Delivery Device/System (Syringe,patch,etc.)
- Device Coated/Impregnated/Otherwise Combined Drug
- Device Coated Or Otherwise Combined With Biologic
- Drug/Biologic Combination
- Separate 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)

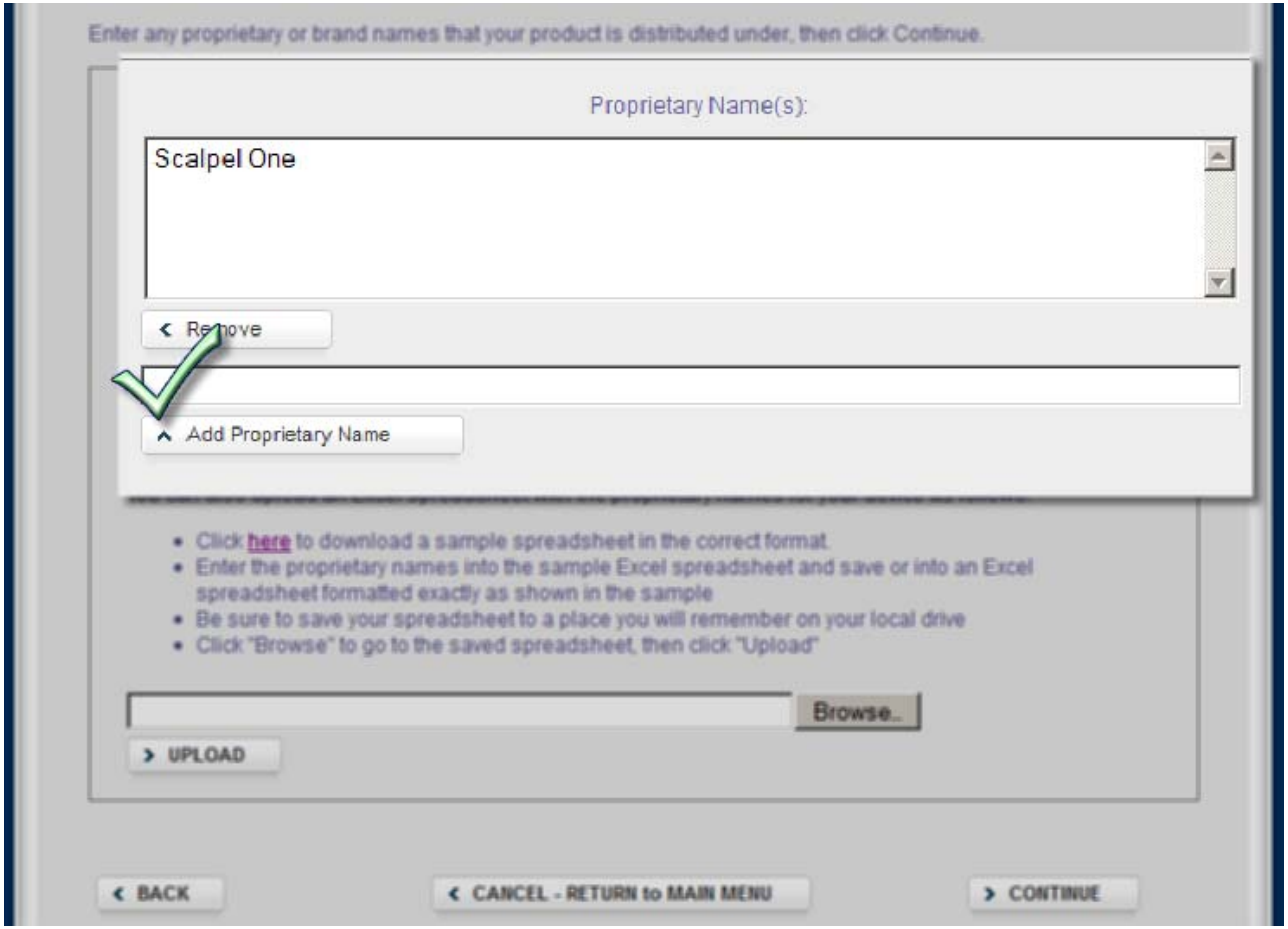
- Descriptions for type of combination product can be found at: http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm

Step 10: Select Facility

Step 11: Select Activity



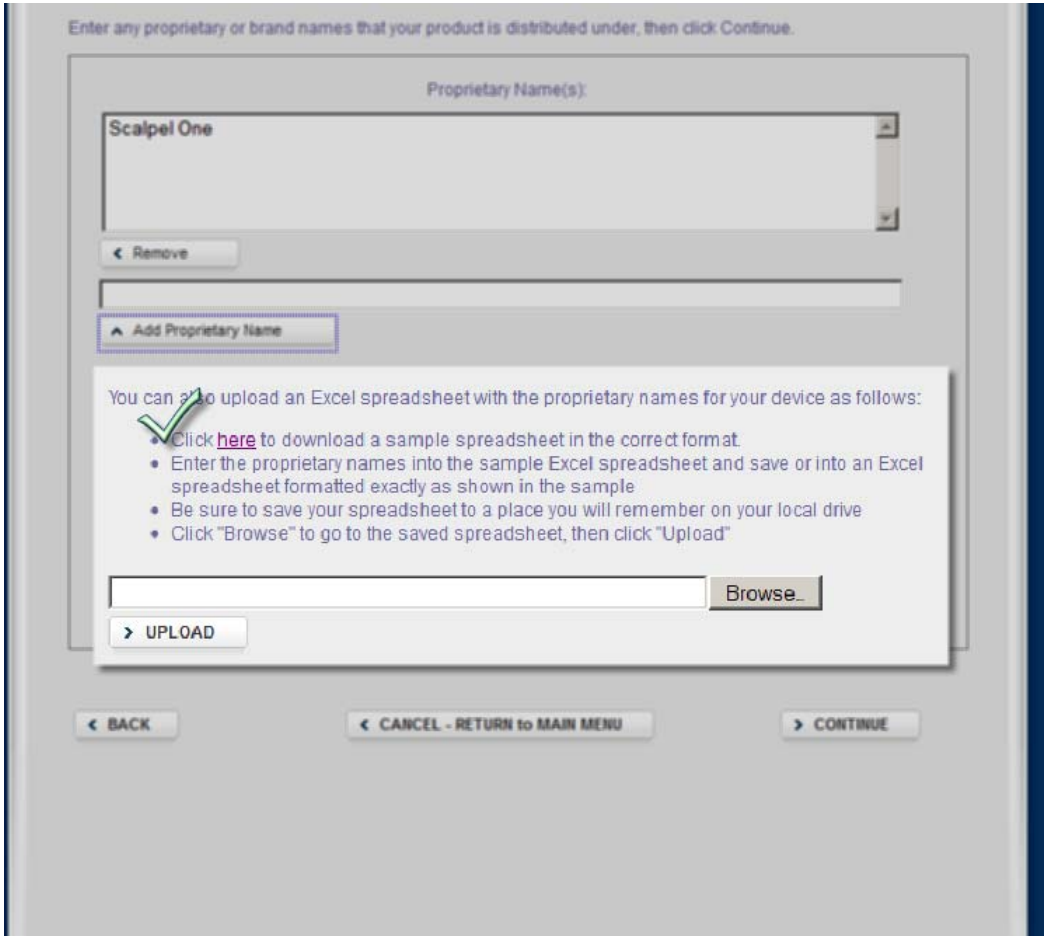
Step 12: Add Proprietary Name



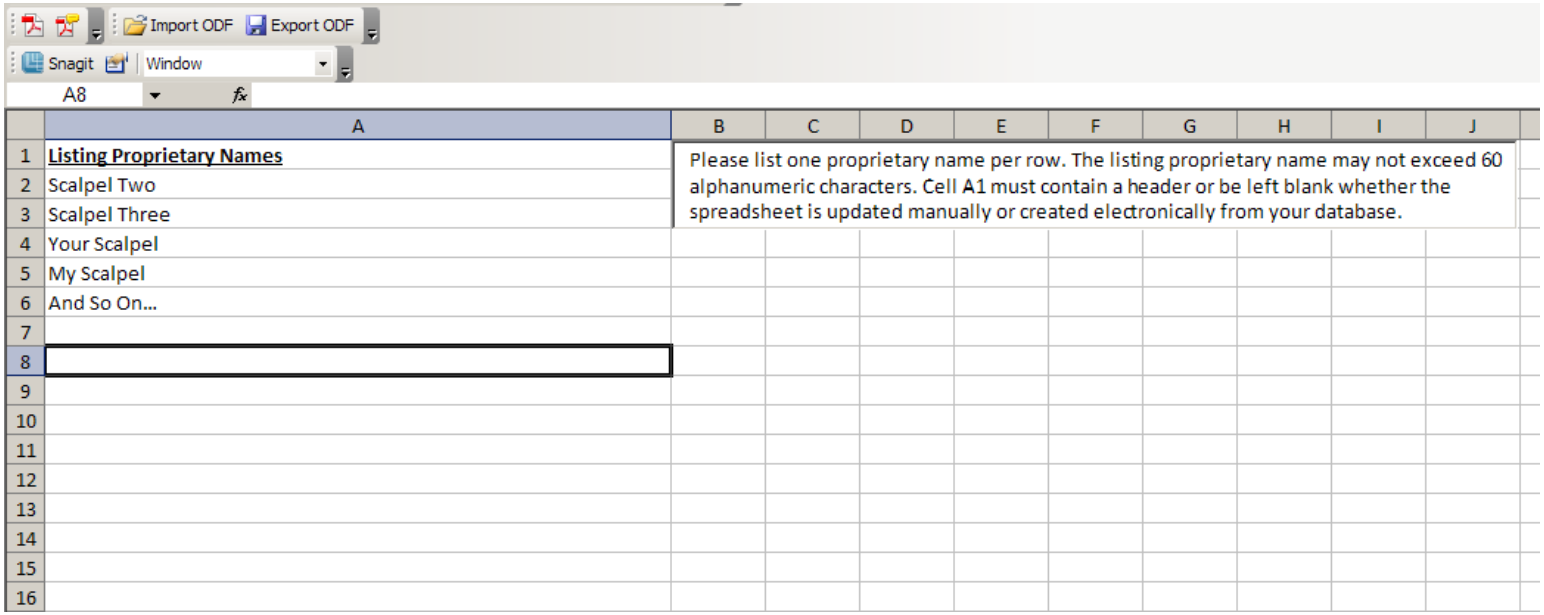
Adding Proprietary Names

- 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

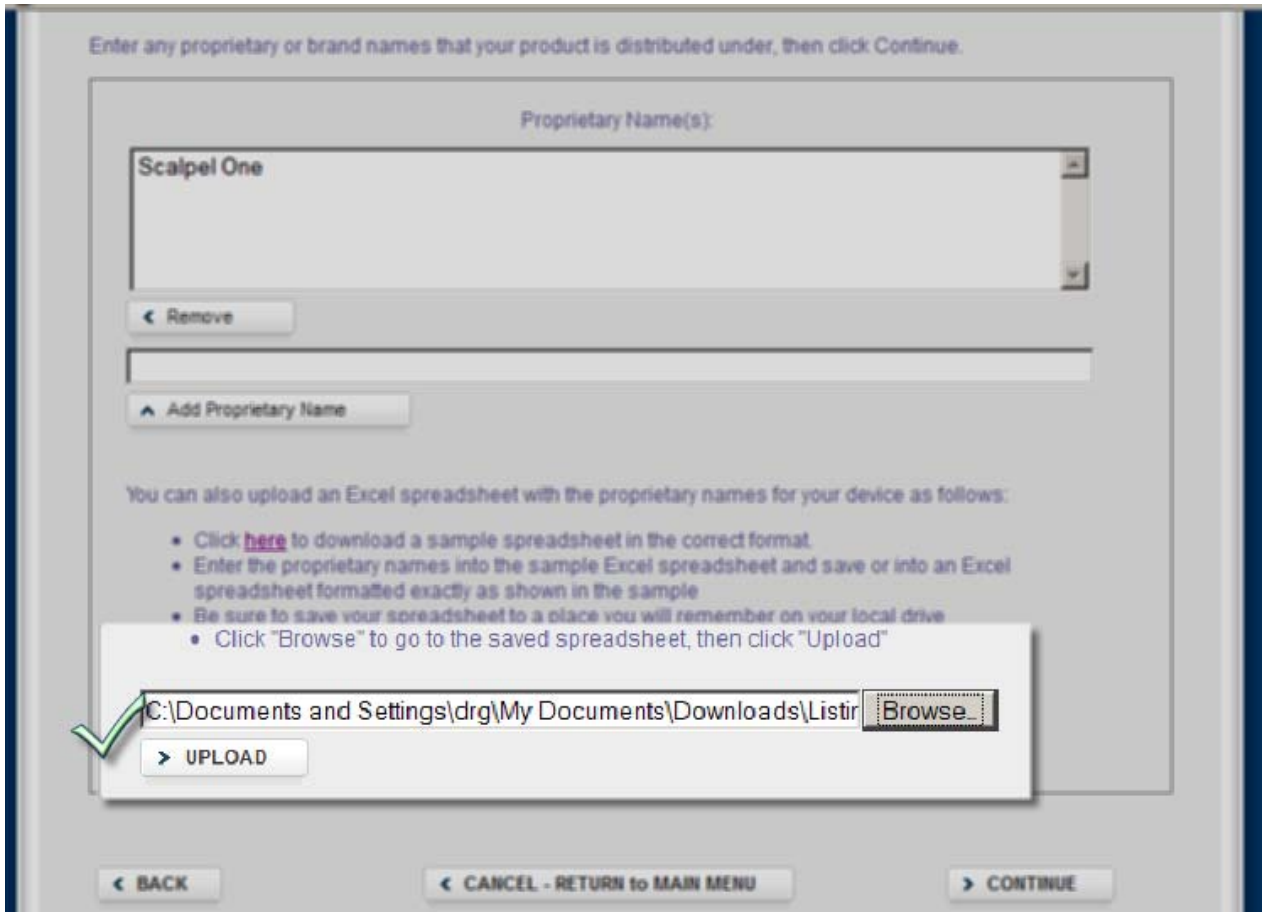


Adding Proprietary Names: Sample Format

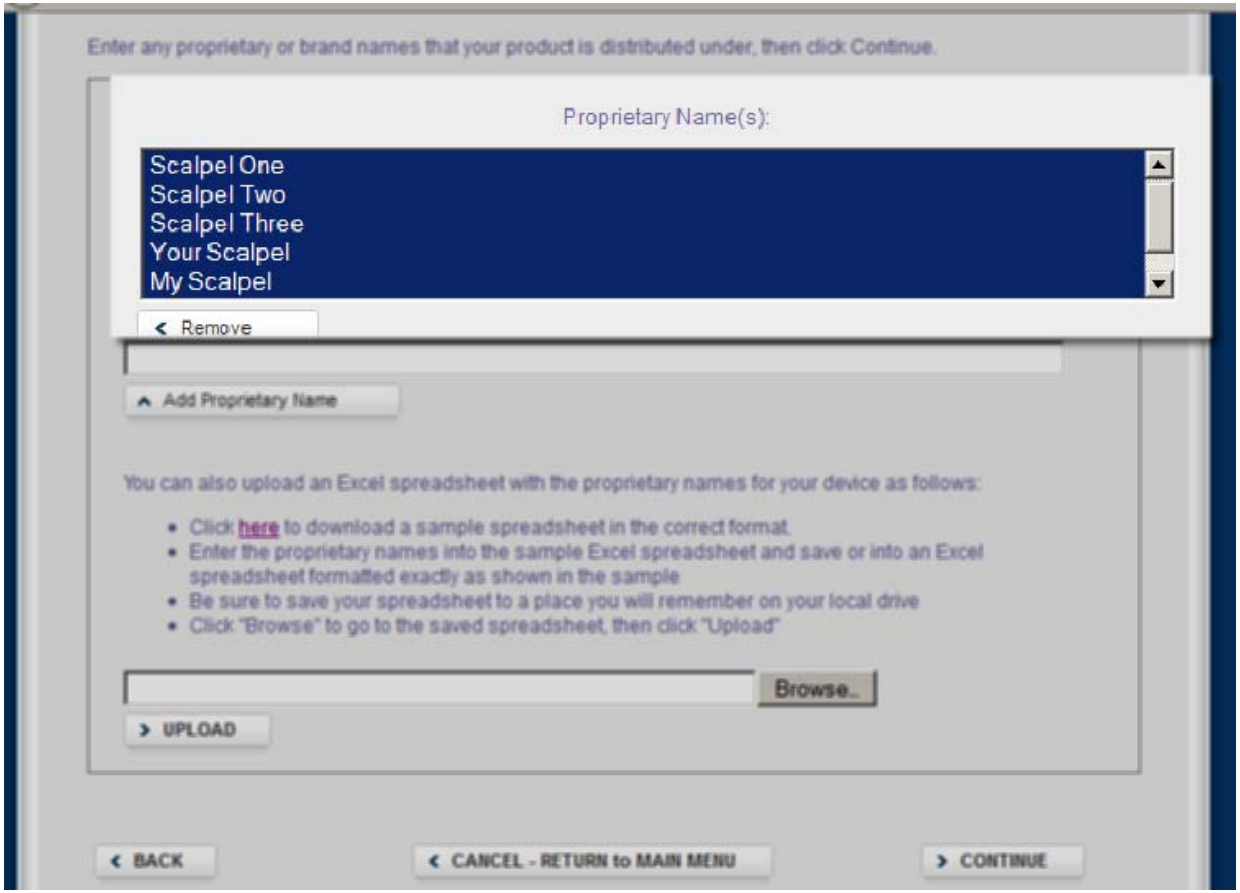


Save to a folder/location you will remember

Upload Excel File With Names



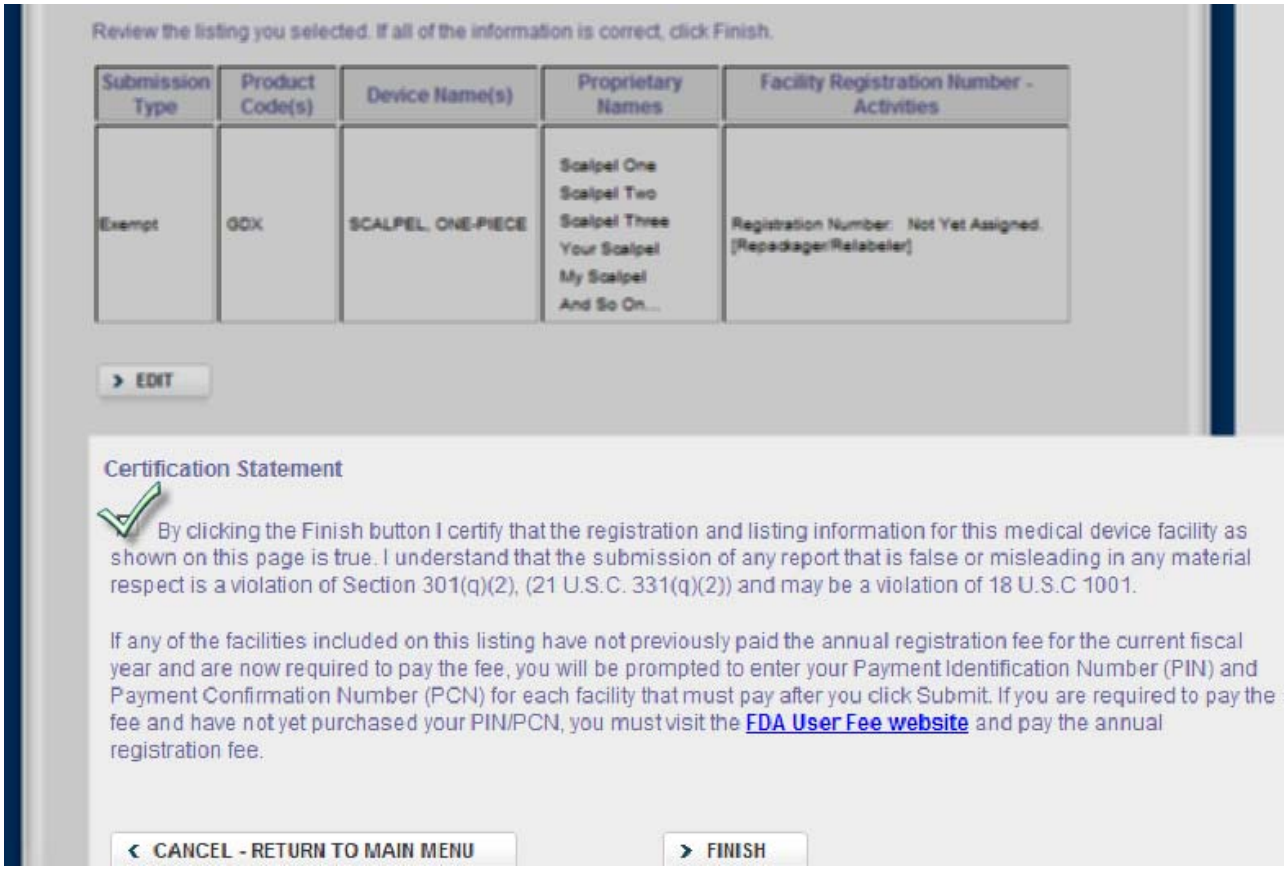
Upload Excel File With Names - Result



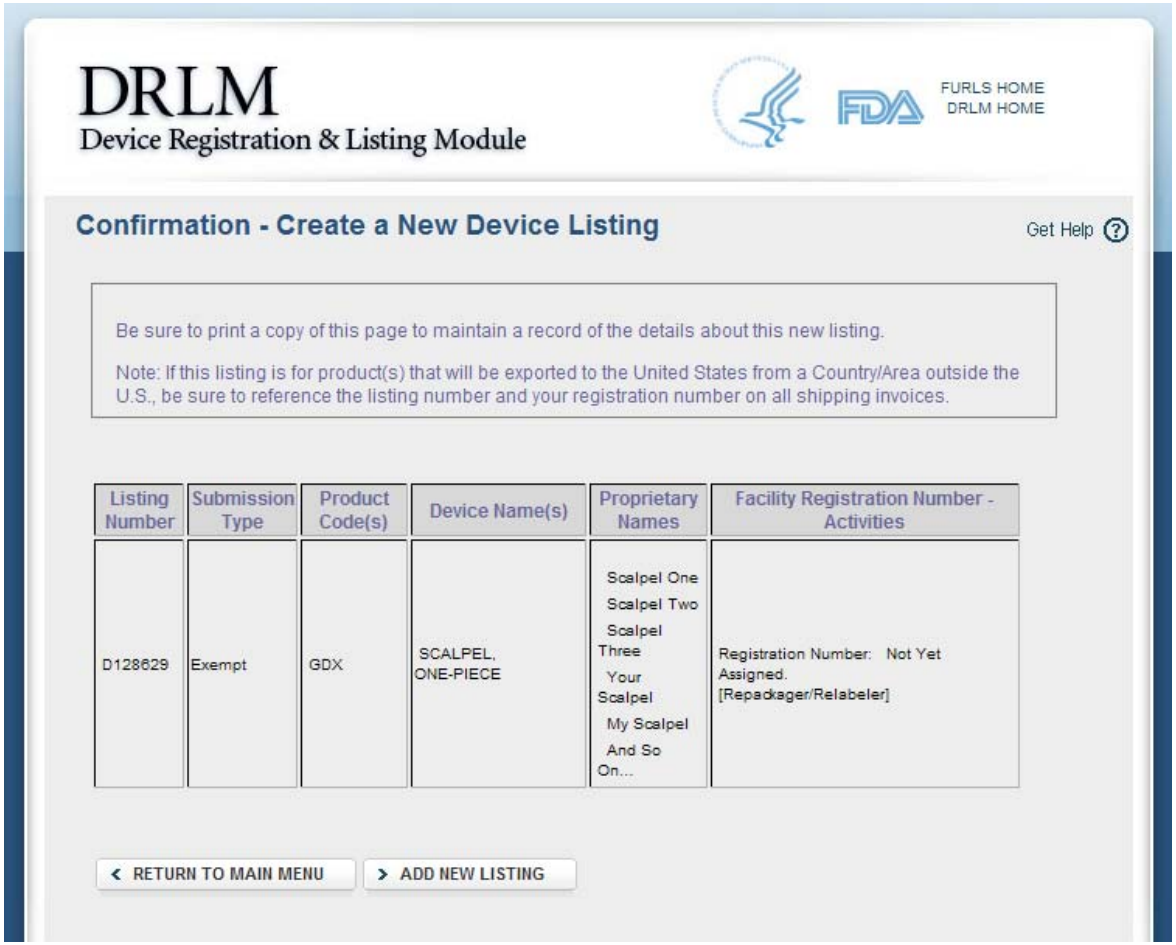
Adding Proprietary names: Sample Format (cont'd.)

- 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



Step 14: Listing Confirmation



DRLM
Device Registration & Listing Module

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
D128629	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

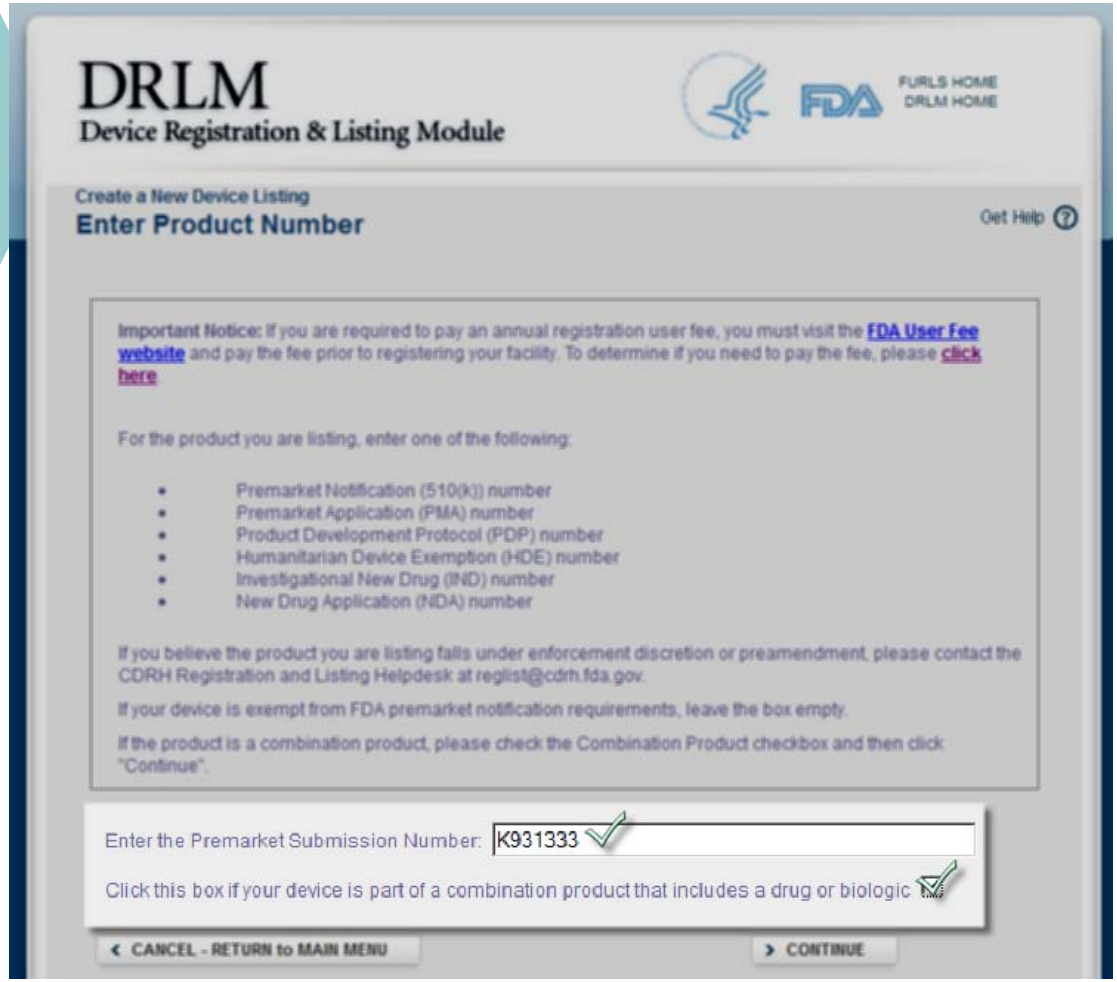
Create Listing – Non-exempt Combination Product

- 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

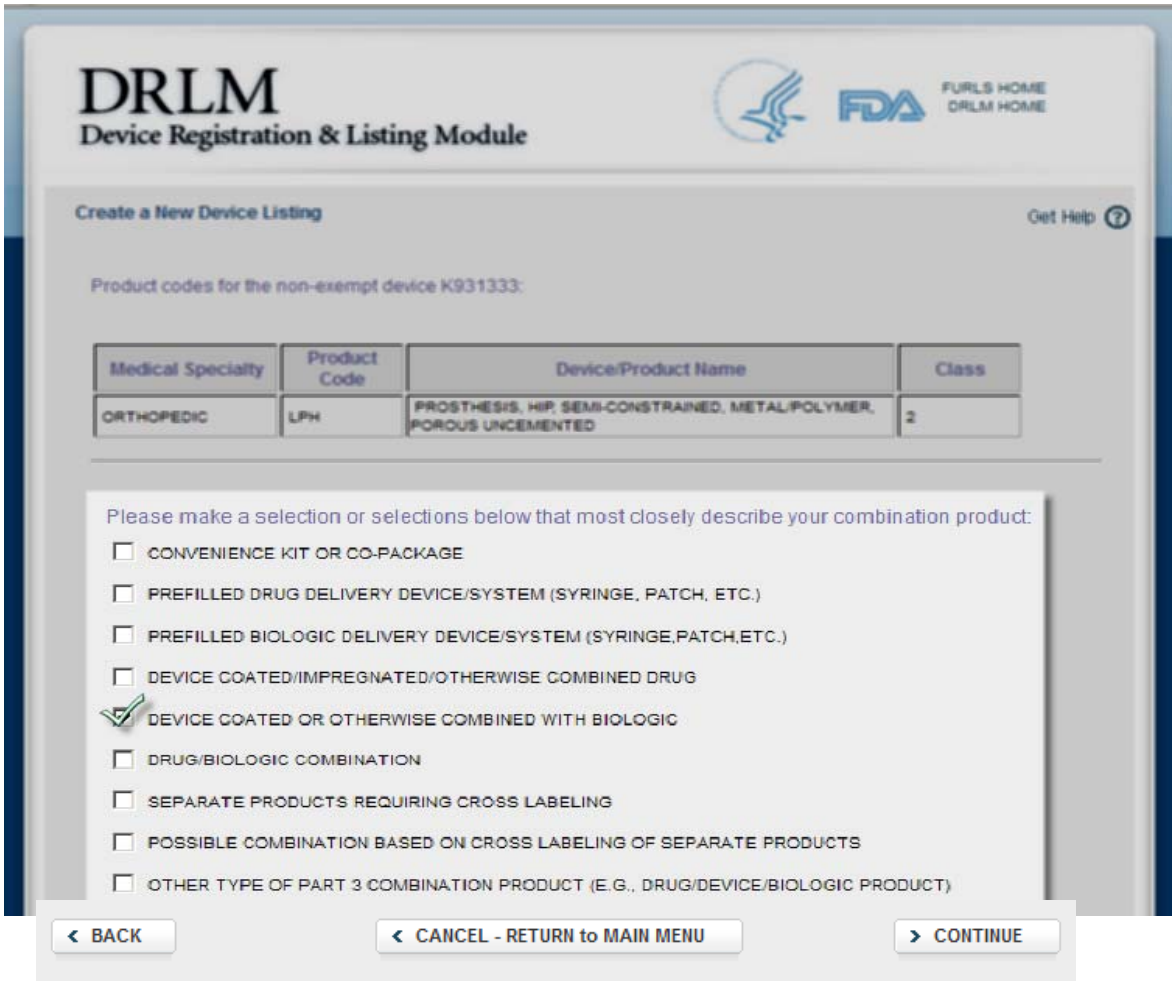
- Step 1: Log into FURLS/DRLM
- Step 2: Click on “Device Registration and Listing”
- Step 3: Click on “Continue” on page with red text

Step 4: Enter Premarket Submission Number



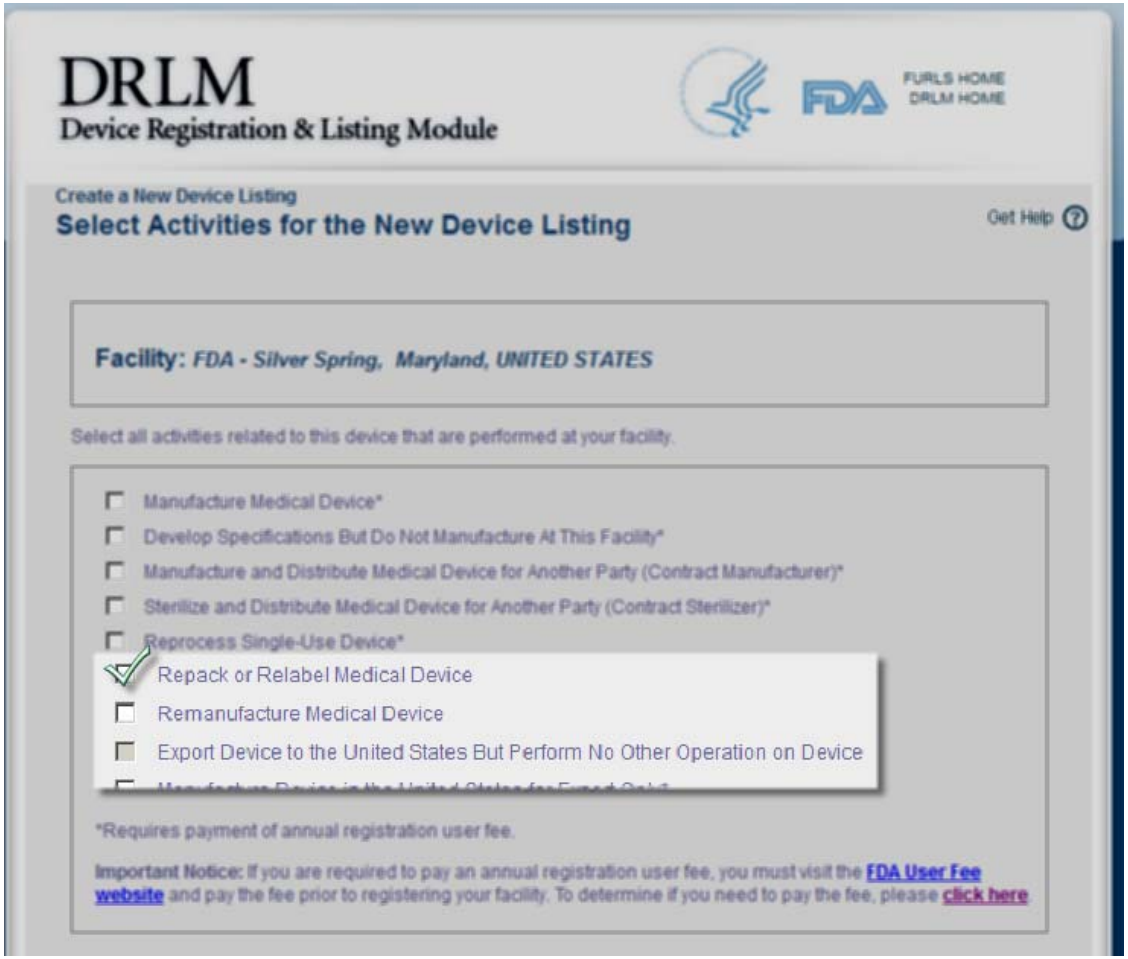
If device is combination product in premarket database, firm can go to the next screen where they identify the type of combination product

Step 5: Check type of combination product

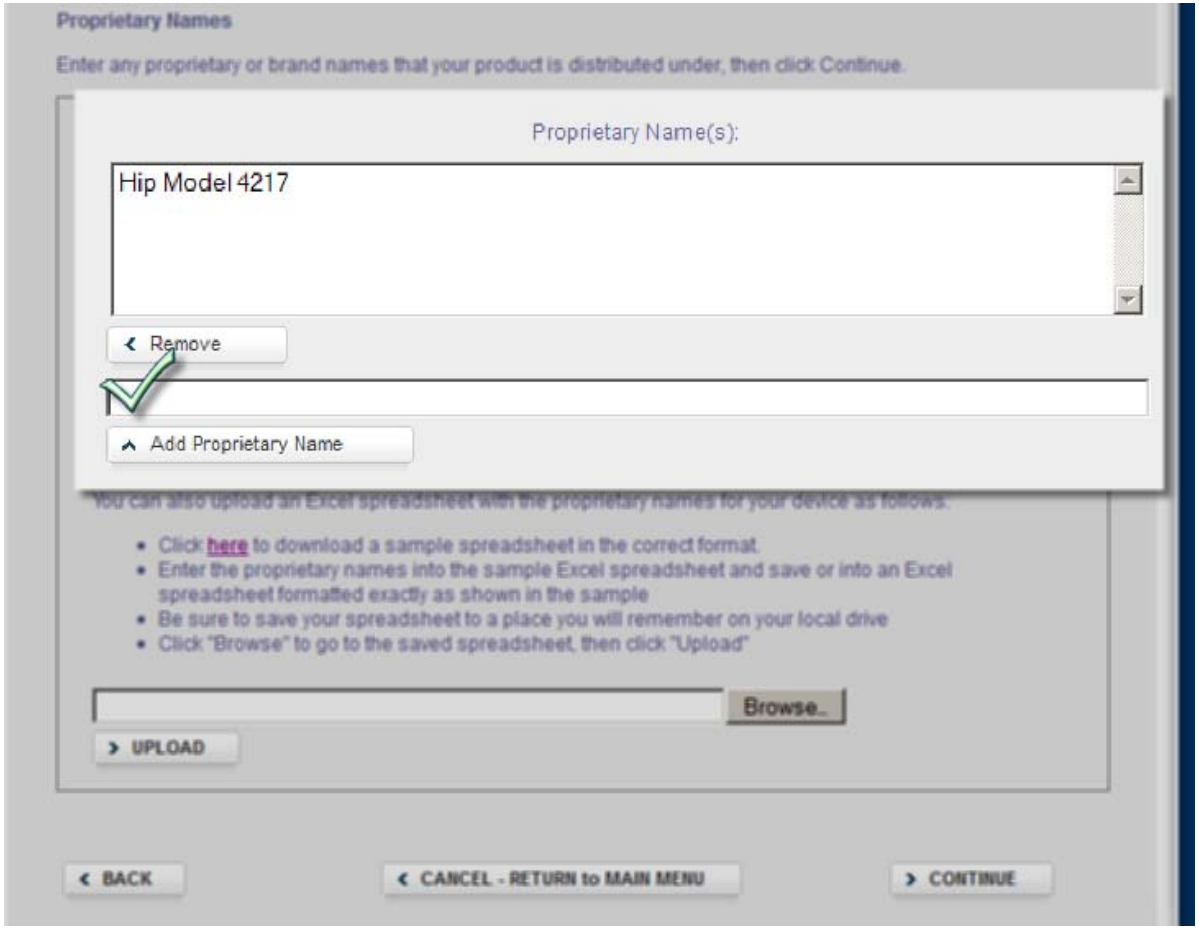


Step 6: Select Facility

Step 7: Select Activity

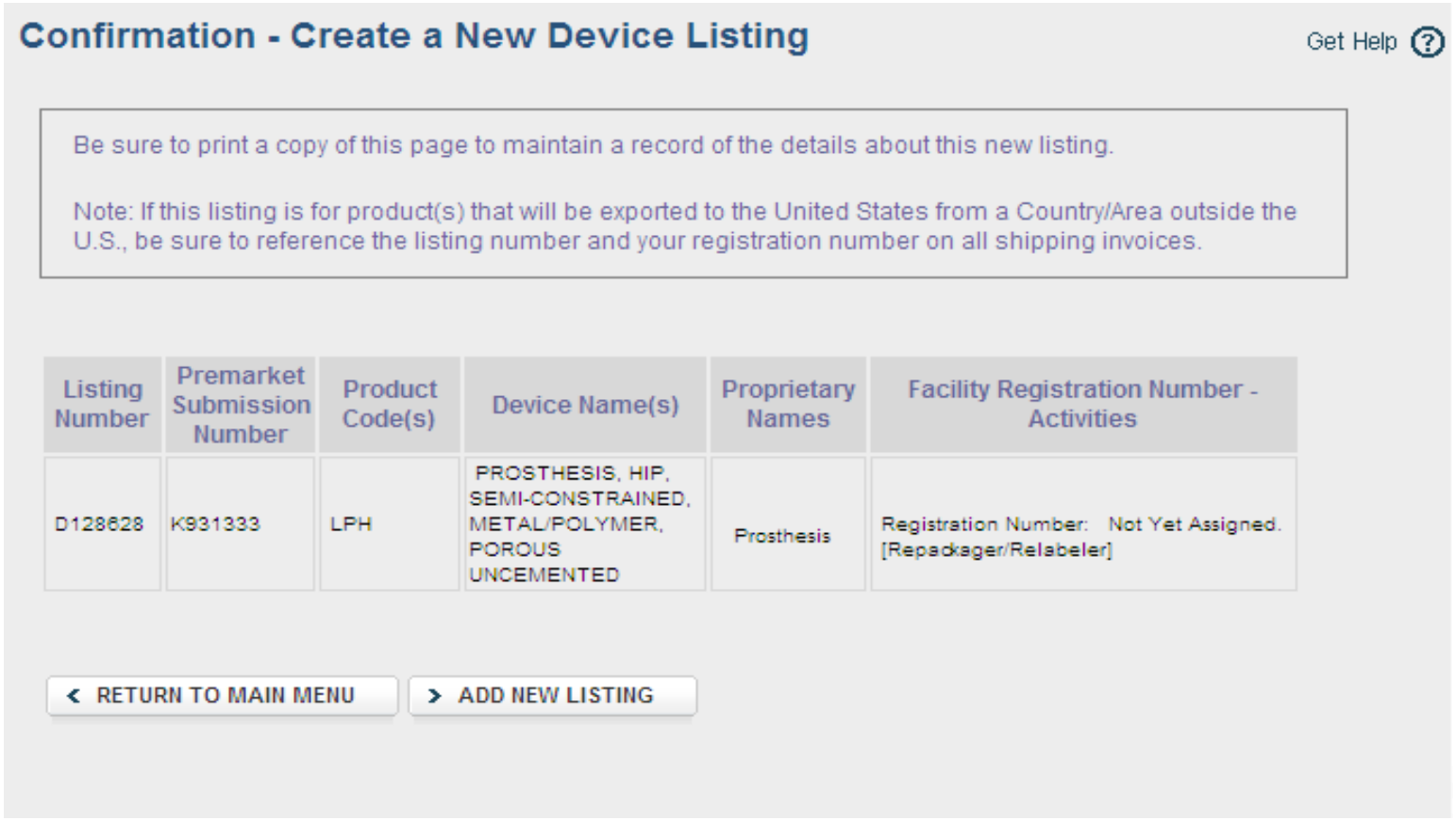


Step 8: Add Proprietary Name



Step 9: Review Listing

Step 10: Listing Confirmation



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.

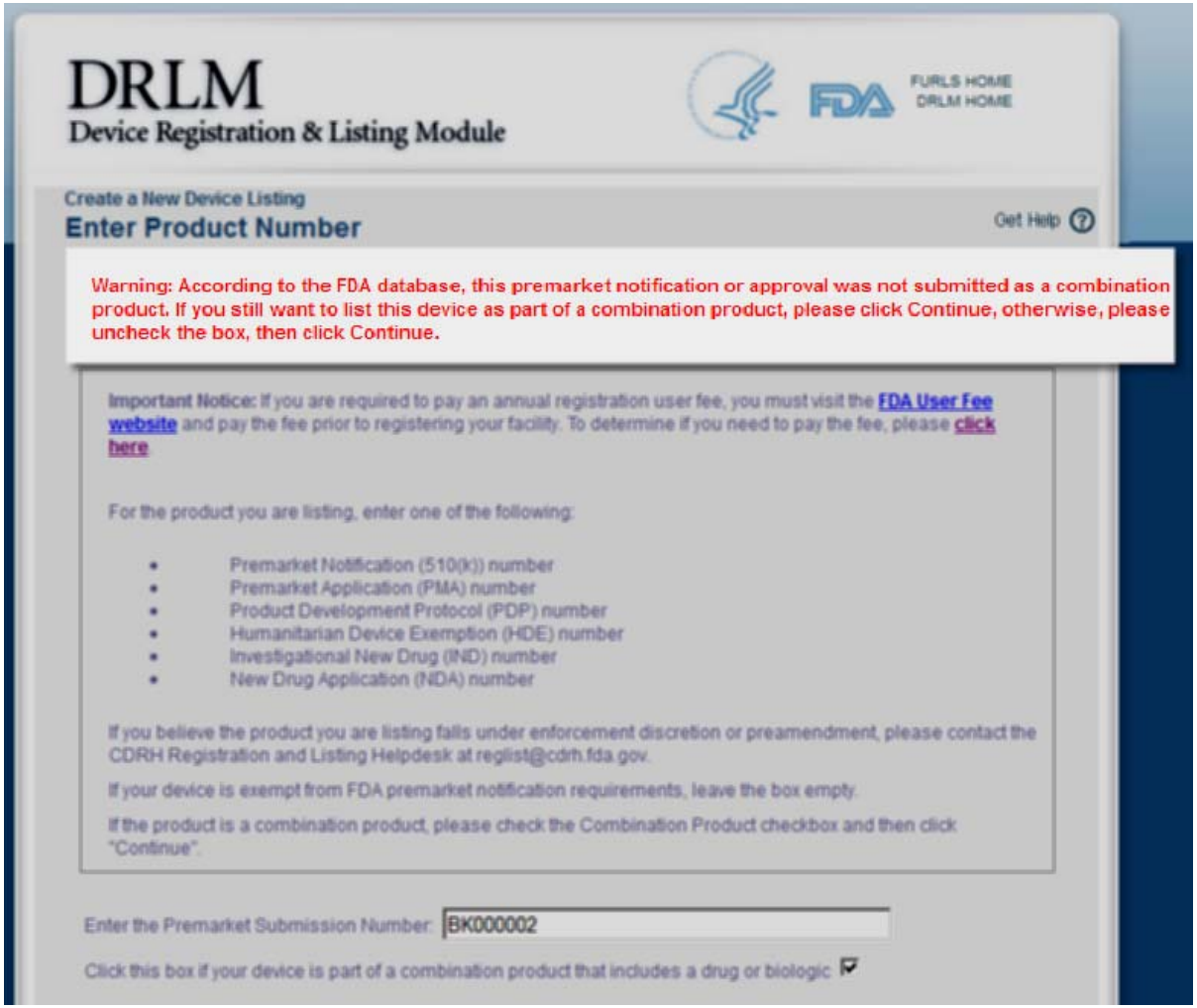
Listing Number	Premarket Submission Number	Product Code(s)	Device Name(s)	Proprietary Names	Facility Registration Number - Activities
D128628	K931333	LPH	PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, POROUS UNCEMENTED	Prosthesis	Registration Number: Not Yet Assigned. [Repackager/Relabeler]

< 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



Questions about Listing Combination Products

- If you have any questions, please contact the CDRH Registration and Listing Helpdesk by email at reglist@cdrh.fda.gov.