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

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

- [ ] YES
- [x] NO
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

![Image of DRLM Device Registration & Listing Module interface with 'scalpel' entered and filtered results]

- 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.
Step 9: Check box that describes 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)
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

| 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 Point

*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
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

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

1. Click [here](#) to download a sample spreadsheet in the correct format.
2. Enter the proprietary names into the sample Excel spreadsheet and save or open it.
3. Be sure to save your spreadsheet to a place you will remember on your local drive.
4. Click "Browse" to go to the saved spreadsheet, then click "Upload".

[Upload button]

[Back]  [Cancel - Return to Main Menu]  [Continue]
Adding Proprietary Names: Sample Format

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Listing Proprietary Names</td>
</tr>
<tr>
<td>2</td>
<td>Scalpel Two</td>
</tr>
<tr>
<td>3</td>
<td>Scalpel Three</td>
</tr>
<tr>
<td>4</td>
<td>Your Scalpel</td>
</tr>
<tr>
<td>5</td>
<td>My Scalpel</td>
</tr>
<tr>
<td>6</td>
<td>And So On...</td>
</tr>
<tr>
<td>7</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
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<td>10</td>
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<td>13</td>
<td></td>
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<tr>
<td>14</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** 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.

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

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\List

> UPLOAD
Upload Excel File With Names - Result

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."
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.

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

Confirmation - Create a New Device Listing

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.

<table>
<thead>
<tr>
<th>Listing Number</th>
<th>Submission Type</th>
<th>Product Code(s)</th>
<th>Device Name(s)</th>
<th>Proprietary Names</th>
<th>Facility Registration Number - Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>D123456</td>
<td>Exempt</td>
<td>001</td>
<td>SCALPEL, ONE PIECE</td>
<td>Scalpel One</td>
<td>Registration Number: Not Yet Assigned [Repackager/Relabeled]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Scalpel Two</td>
<td></td>
</tr>
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</tbody>
</table>

< 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

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
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- POSSIBLE COMBINATION BASED ON CROSS LABELING OF SEPARATE PRODUCTS
- OTHER TYPE OF PART 2 COMBINATION PRODUCT (E.G., DRUG/DEVICE/BIOLOGIC PRODUCT)
Step 6: Select Facility
Step 7: Select Activity

DRLM Device Registration & Listing Module

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
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*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 8: Add Proprietary Name
Step 9: Review Listing

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

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.

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Step 10: Listing Confirmation

Confirmation - Create a New Device Listing

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.

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<th>Device Name(s)</th>
<th>Proprietary Names</th>
<th>Facility Registration Number - Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>D128626</td>
<td>K931333</td>
<td>LPH</td>
<td>PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, POROUS UNCEMENTED</td>
<td>Prosthesis</td>
<td>Registration Number: Not Yet Assigned. [Repackager/Relabeler]</td>
</tr>
</tbody>
</table>

< 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.
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.

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: BK0000002

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