

Hibiscus | Device Pass-through

Initial Info

Device Info

FDA Info

Cost Info

Volume and Utilization

Substantial Clinical Improvement

Summary

Who is the primary contact?

First name	Middle name (optional)	Last name
US Phone Number Ex. 1234567890	Extension (optional)	Country United States
Email address		
Mailing address line 1		
Mailing address line 2 (optional)		
City	State	ZIP code
Organization (optional)		
Relationship		

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Who is the secondary contact?

First name	Middle name (optional)	Last name
US Phone Number Ex: 1234567890	Extension (optional)	Country United States
Email address		
Mailing address line 1		
Mailing address line 2 (optional)		
City	State	ZIP code
Organization (optional)		
Relationship		

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Have you completed other MEARIS™ applications for this device?



Yes



No

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Clicking “Yes” will take you to this page:

MEARIS™
Medicare Electronic Application
Request Information System

Home Tasks Applications Teams

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Provide information about your previous applications

Application type Application status (optional)

Description

Submission date (Optional)

Add Application

Previous application list
It looks like there is nothing here

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Provide information about your previous applications

Application type	Application status (optional)
Description	
Submission date (Optional)	

Add Application

Previous application list

New Technology Add-on Payments (NTAP) Approved Application Description	05/05/2021	Remove
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MEARIS™
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What is the name or description and additional details of the proposed device category?

Category name/description

Ambulatory Payment Classification (APC) assignment (optional)

[Click to see device category requirements](#)

Back Next

Provide information about a device nominated to fit the proposed additional category.

Device Trade/Brand Name

Device type

Is the device used for diagnosis or treatment?

- Diagnosis
- Treatment
- Both

What is the device? what does it do? what is it used for? and how is it used?

Answer

0 / 2000

For what disease processes and patient populations is the device used?

Answer

0 / 2000

What are the complications associated with the device's use?

Answer

0 / 2000

Provide a complete physical description of the device including its components, e.g., hardware, software, reservoir, tubing, its composition, coating, or covering.

Answer

0 / 2000

What is the device's life span?

Answer

0 / 2000

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Next

Using Healthcare Common Procedure Coding System (HCPCS) Level I and/or Level II code(s), list all of the specific procedure(s) and/or services with which the nominated device is used.

Enter HCPCS codes and titles

 [HCPCS General Info](#)

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Are there any established device categories used presently or previously for pass-through payment that describe related or similar products?



Yes



No



[View established device categories](#)

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Describe the established device category(s) and provide a detailed explanation as to why that category does not encompass the nominated device.

Answer

0 / 2000

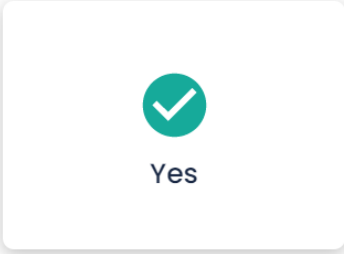
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Does the device replace or improve upon an existing device?



Yes



No

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List existing devices including trade/brand name and any HCPCS Level I and/or Level II code(s) used to identify the existing device.

Enter device details to add them to the list.

Device Trade/Brand Name _____

Enter HCPCS codes titles _____

What makes your device different?

Answer

0 / 2000

Add to list

List of existing devices

Back **Next**

List existing devices including trade/brand name and any HCPCS Level I and/or Level II code(s) used to identify the existing device.

Enter device details to add them to the list.

Device Trade/Brand Name

Enter HCPCS codes titles

What makes your device different?

Answer

0 / 2000

Add to list

List of existing devices

+ Device Name

Remove

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Are there similar devices that would also become eligible for transitional pass-through payment under the proposed additional category?

 **Yes**

 **No**

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Identify by name and manufacturer similar devices that would also become eligible for transitional pass-through payment under the proposed additional category.

Answer

0 / 2000

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Please upload all relevant booklets, pamphlets, brochures, product catalogs, price lists, and/or package inserts that further describe and illuminate the nature of the nominated device.

List of Files for Device Info
There are no files, please click the button below to add a referencing file.

[Add/Edit File\(s\)](#)

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Please upload all relevant booklets, pamphlets, brochures, product catalogs, price lists, and/or package inserts that further describe and illuminate the nature of the nominated device.

Select an existing or attach a new file.

Please Upload a file to save
Supported formats include PDF, word, excel, powerpoint, JPEG, PNG, and plain text file(s)

Drag and drop a file to upload or [Browse File](#)

Provide some details about the selected file

Page number(s) _____

Summarize the supporting information contained in this file

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Please upload all relevant booklets, pamphlets, brochures, product catalogs, price lists, and/or package inserts that further describe and illuminate the nature of the nominated device.

List of Files for Device Info

+ Applications Locator.png Delete

Add/Edit File(s)

Back **Next**

Provide details about your most recent FDA application for the nominated device.

Select your most recent FDA Marketing Pathway.

Select one

Other

Provide your Investigational Device Exemption (IDE) number.

IDE number (optional)

Provide the FDA decision date.

Decision date

Provide additional information regarding your alternate regulatory pathway, providing the complete citation of the guidance level documentation.

Answer

0 / 2000



The FDA decision date (or in certain documented cases U.S. market availability) must be within 3 years of the application date for transitional pass-through payment.

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Please upload all FDA supporting documents

Items to include are the FDA decision letter, summary of safety and effectiveness, complete citation documentation, and guidance level documentation

List of Files for FDA Info

There are no files, please click the button below to add a referencing file.

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Please upload all FDA supporting documents

Items to include are the FDA decision letter, summary of safety and effectiveness, complete citation documentation, and guidance level documentation

Select an existing or attach a new file.

Please Upload a file to save
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Please upload all FDA supporting documents

Items to include are the FDA decision letter, summary of safety and effectiveness, complete citation documentation, and guidance level documentation

List of Files for FDA Info

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What is the current cost of the entire device to hospitals?

\$ Current Total Cost



Current cost of the device to hospitals should be the actual cost paid by hospitals for the device net of all discounts, rebates, and incentives in cash or in kind.

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Provide the current cost of each individual component of the device to hospitals.

Enter component details to add them to the list.

Item		
\$ Current Cost	Classification	▼

Add Item

The following is a list of components

Looks like there is nothing here. Add an item above.

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If applicable, summarize any partial systems created by the components you listed.

Summary (optional)



0 / 2000

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Next

Provide a detailed explanation for each cost subtest, including the calculations.

1) Is the device cost at least 25% of the applicable APC payment rate to reach cost significance?
(Highest Retail cost on application / Lowest APC rate available) x 100 = __ Percent

Answer

0 / 2000

2) Is the device cost at least 125% of the offset amount (the device related portion of the APC found on the offset list)?
(Highest Retail cost on application / Offset amount) x 100 = __ Percent

Answer

0 / 2000

3) Is the device cost minus the APC offset amount divided by the APC payment amount at least 10% of the APC payment amount?
(Highest Retail cost on application - Offset amount) / APC payment) x 100 = __ Percent

Answer

0 / 2000

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Please upload all cost supporting documents.

List of Files for Cost Info

There are no files, please click the button below to add a referencing file.

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Select an existing or attach a new file.

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Please upload all cost supporting documents.

List of Files for Cost Info

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Provide sales and marketing information about the nominated device.

What date was the device first marketed in the United States and/or outside the United States?

US marketing date

International marketing date (optional)

What date was the device's first sale in the United States and/or outside the United States?

US sale date (optional)

International sale date (optional)

Was there a market availability delay for the device?

Yes No

Provide details of the market availability delay.

Details

0 / 2000

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Provide volume data for the proposed device category.

How many units of the nominated device have been sold to date?

Number of units

How many facilities use the nominated device?

Number of facilities

Please outline the projected total annual utilization for both the nominated device and proposed device category as a whole.

Outline

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For each HCPCS code associated with the device, provide an estimate annual utilization by the site of service.

For example, HCPCS code XYZ has a projected utilization of:
200 hospital outpatient, 300 ambulatory surgical center, 10 hospital inpatient, 500 physician office.

HCPCS Code

Hospital Outpatient	Ambulatory Surgical Center
<input type="text" value="12"/>	<input type="text" value="12"/>
Hospital Inpatient	Physician Office
<input type="text" value="12"/>	<input type="text" value="12"/>
Other (optional)	
<input type="text" value="12"/>	
Define what the "Other" utilization category is	
<input type="text" value="Explanation"/>	

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Next

Please upload all volume and utilization supporting documents.

List of Files for Volume and Utilization

There are no files, please click the button below to add a referencing file.

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Please upload all volume and utilization supporting documents.

Select an existing or attach a new file.

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Please upload all volume and utilization supporting documents.

List of Files for Volume and Utilization

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Substantial Clinical Improvement Claims

Provide Substantial Clinical Improvement claims and supporting evidence. While we prefer published peer-reviewed clinical trials, we will consider all supporting evidence.

List of Substantial Clinical Improvement Claims

There are no claims, please click the button below to add a claim.

Add Claim



[Click to see Substantial Clinical Improvement guidelines](#)

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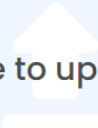
Add a Substantial Clinical Improvement Claim

Short Title of the Substantial Clinical Improvement _____

Select a file or attach a new file as supporting evidence

Please Upload a file to save

Supported formats include PDF, word, excel, powerpoint, JPEG, PNG, and plain text file(s)



Drag and drop a file to upload or

[Browse File](#)


Provide some details about the selected file

Study type _____ Page number(s) _____

Summarize the supporting information contained in this file

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Initial Info Device Info FDA Info Cost Info Volume and Utilization **Substantial Clinical Improvement** Summary


Substantial Clinical Improvement Claims

Provide Substantial Clinical Improvement claims and supporting evidence. While we prefer published peer-reviewed clinical trials, we will consider all supporting evidence.

List of Substantial Clinical Improvement Claims

+ Title	Applications Locator.png	Delete
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[Add Claim](#)

 [Click to see Substantial Clinical Improvement guidelines](#)

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