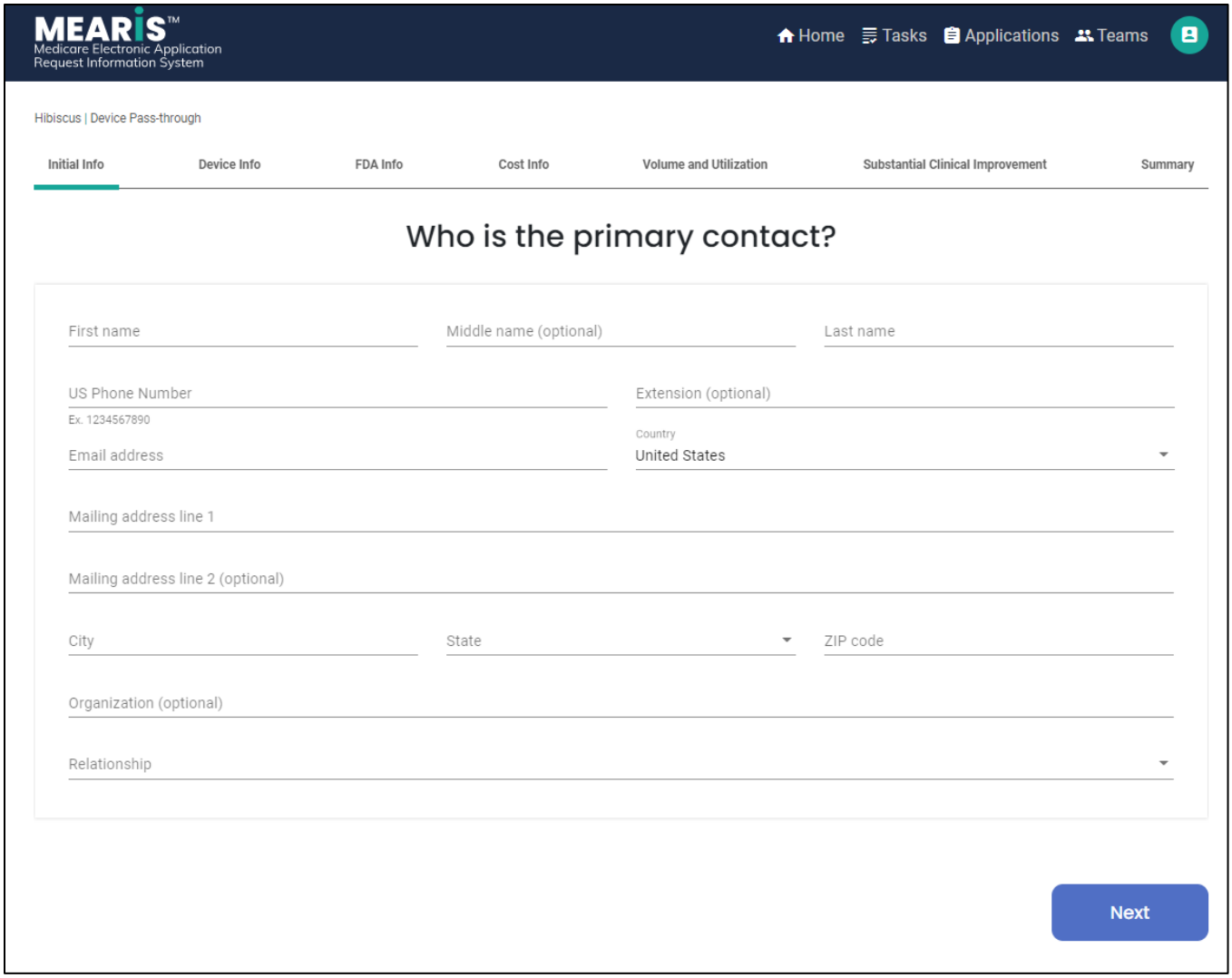
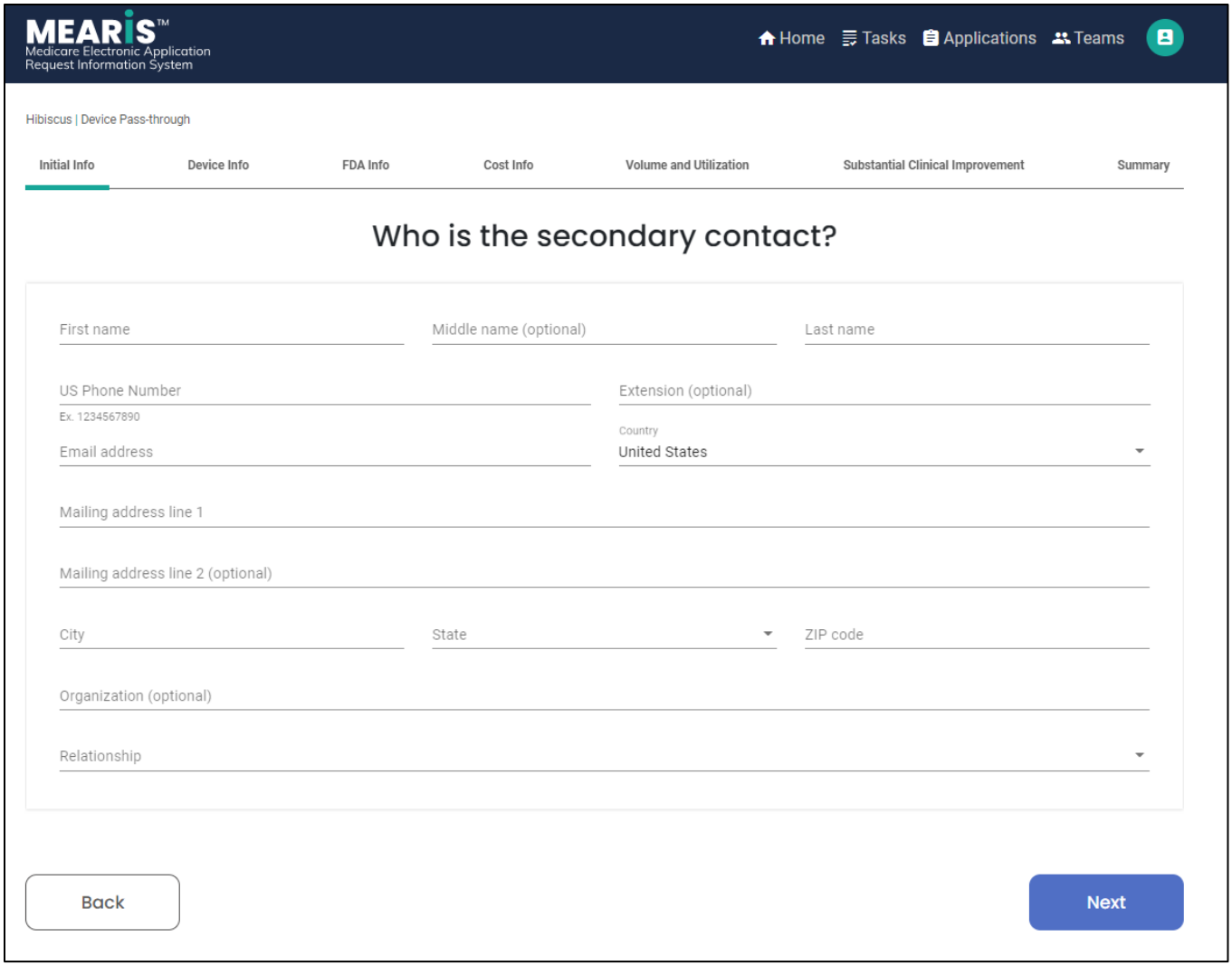

MEARIS™
Medicare Electronic Application Request Information System
Home
Tasks
Applications
Teams
Hibiscus | Device Pass-through
Initial Info
Device Info
FDA Info
Cost Info
Volume and Utilization
Substantial Clinical Improvement
Summary
Who is the primary contact?
First name
Middle name (optional)
Last name
US Phone Number
Ex. 1234567890
Extension (optional)
Email address
Country
United States
Mailing address line 1
Mailing address line 2 (optional)
City
State
ZIP code
Organization (optional)
Relationship
Next


MEARIS™
Medicare Electronic Application Request Information System
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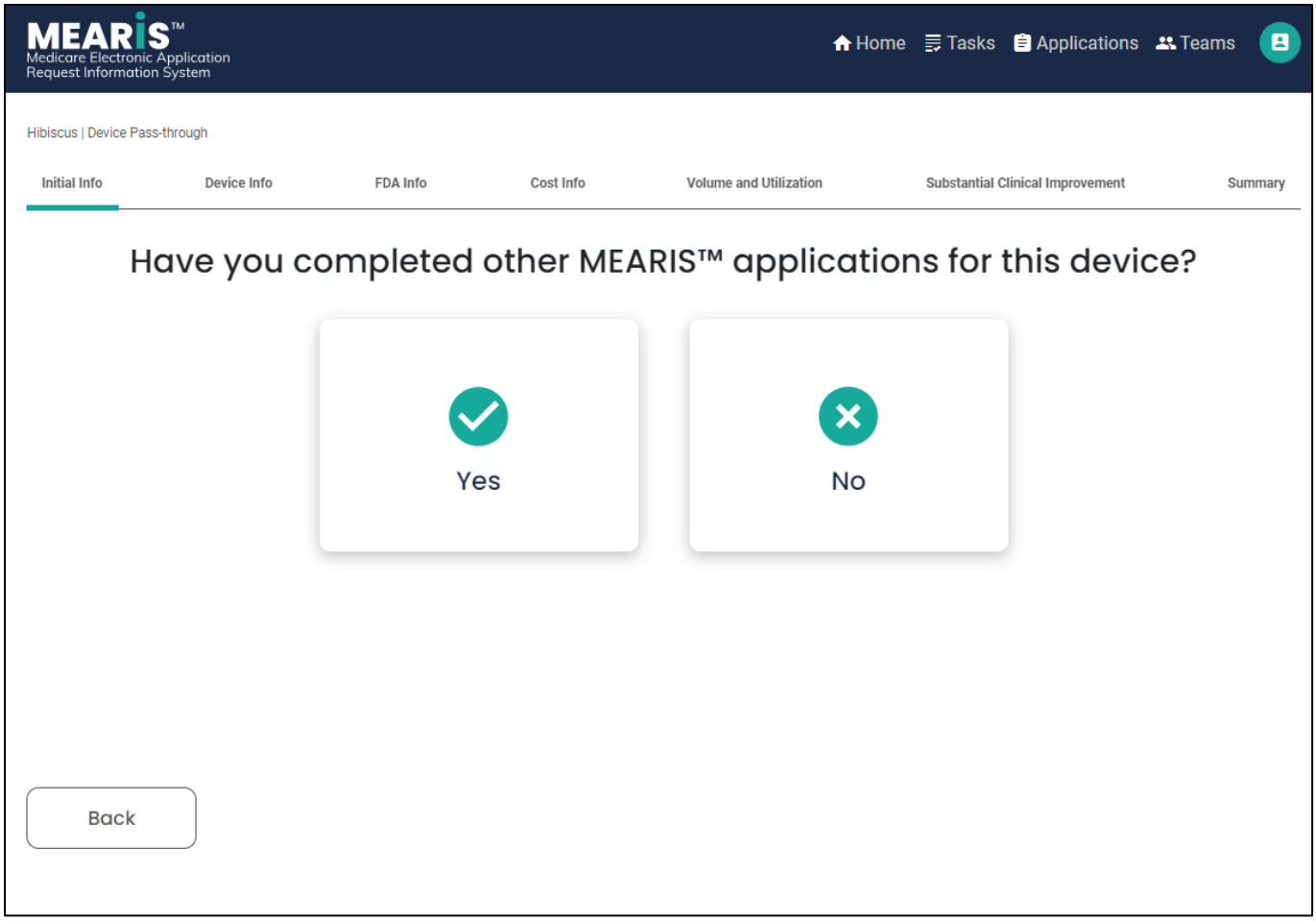
Hibiscus | Device Pass-through
Initial Info
Device Info
FDA Info
Cost Info
Volume and Utilization
Substantial Clinical Improvement
Summary
Who is the secondary contact?
First name
Middle name (optional)
Last name
US Phone Number
Ex. 1234567890
Extension (optional)
Email address
Country
United States
Mailing address line 1
Mailing address line 2 (optional)
City
State
ZIP code
Organization (optional)
Relationship
Back
Next


MEARIS™
Medicare Electronic Application Request Information System
Home
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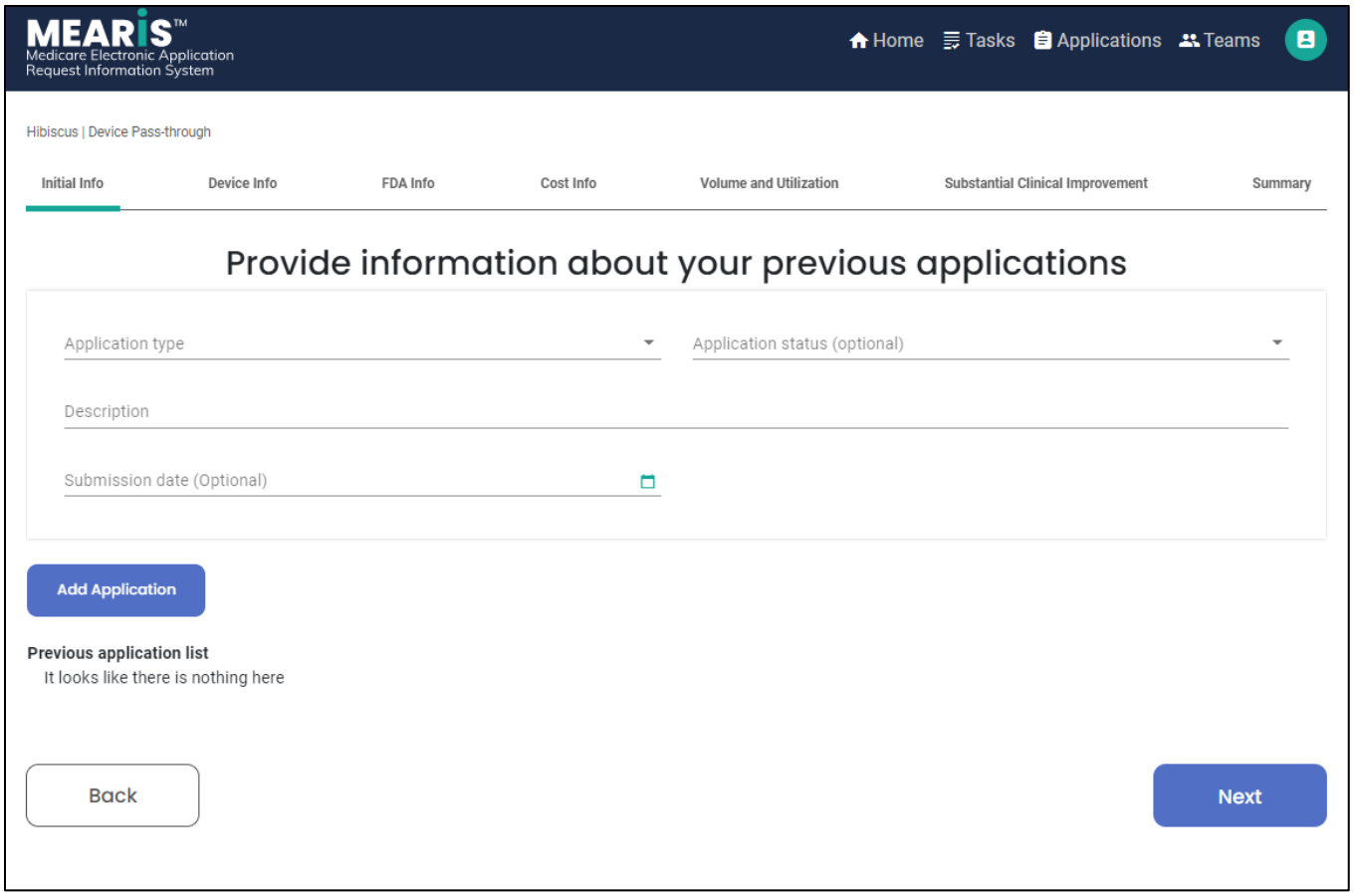
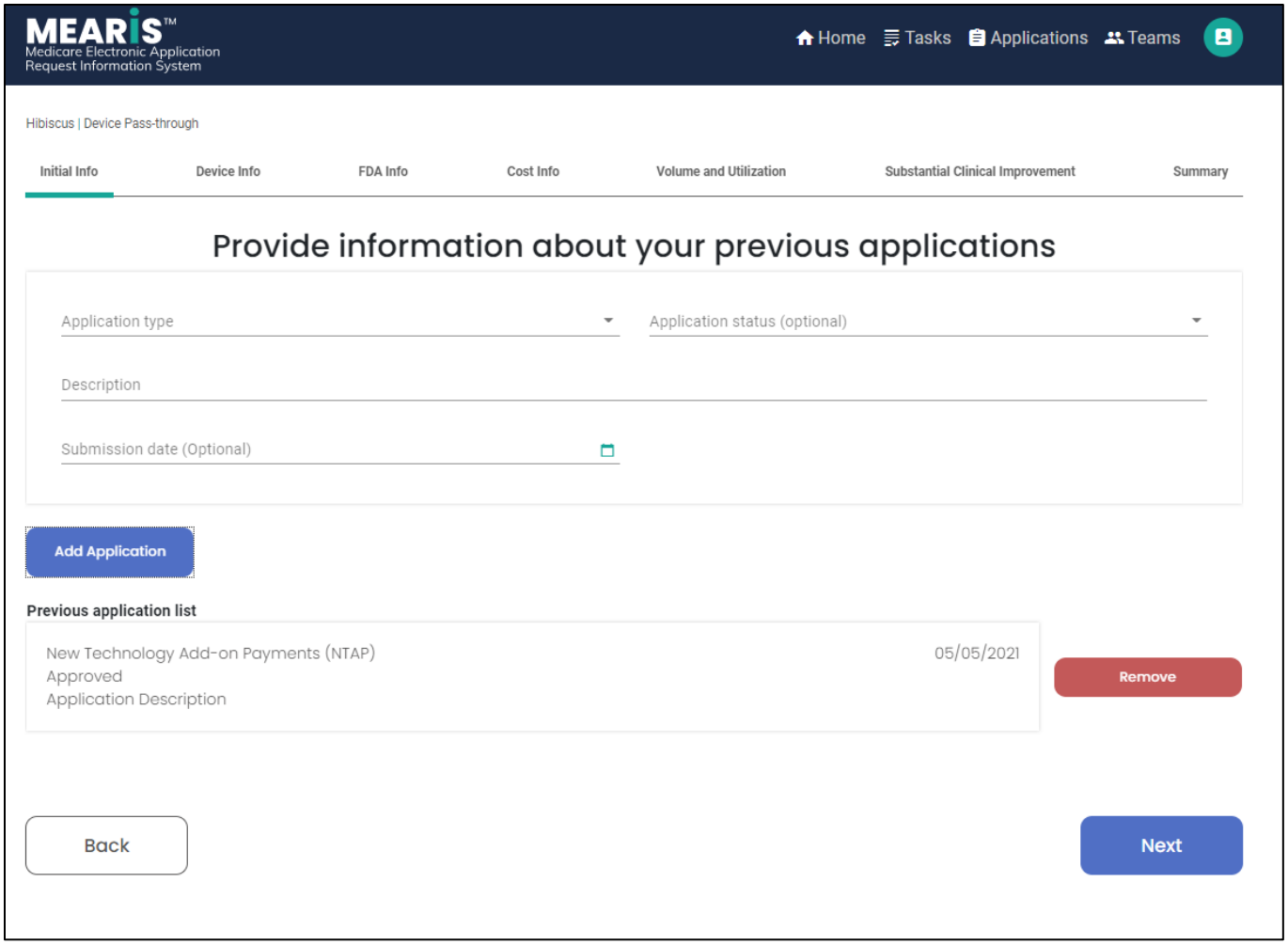
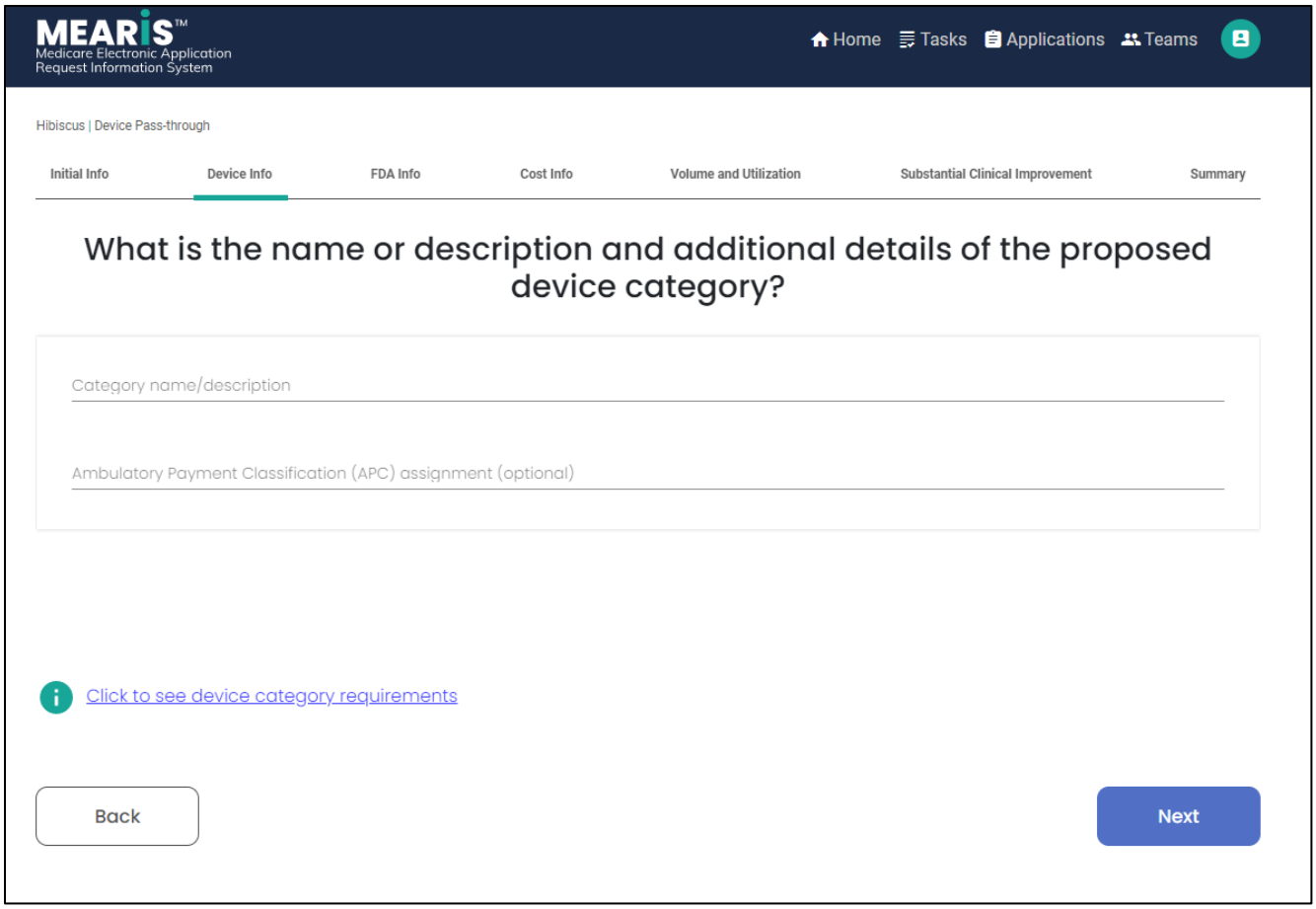
Applications
Teams
Hibiscus | Device Pass-through
Initial Info
Device Info
FDA Info
Cost Info
Volume and Utilization
Substantial Clinical Improvement
Summary
Have you completed other MEARIS™ applications for this device?
Yes
No
Back

Clicking “Yes” will take you to this page:




MEARIS™
Medicare Electronic Application Request Information System
Home
Tasks
Applications
Teams
Hibiscus | Device Pass-through
Initial Info
Device Info
FDA Info
Cost Info
Volume and Utilization
Substantial Clinical Improvement
Summary
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
Back
Next

Clicking “No” will take you to this page:



Hibiscus | Device Pass-through

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

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

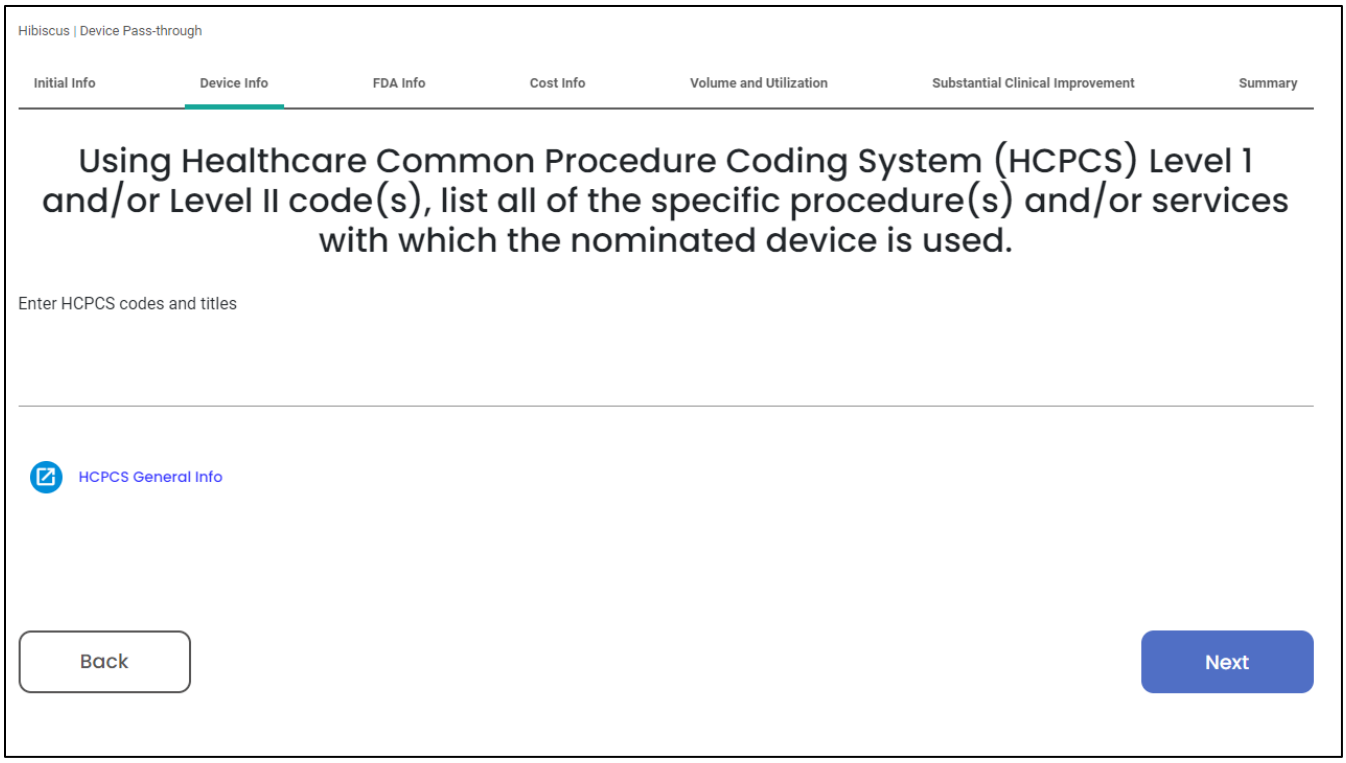
What is the device's life span?

Answer

0 / 2000

Back

Next


Hibiscus | Device Pass-through
Initial Info
Device Info
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Volume and Utilization
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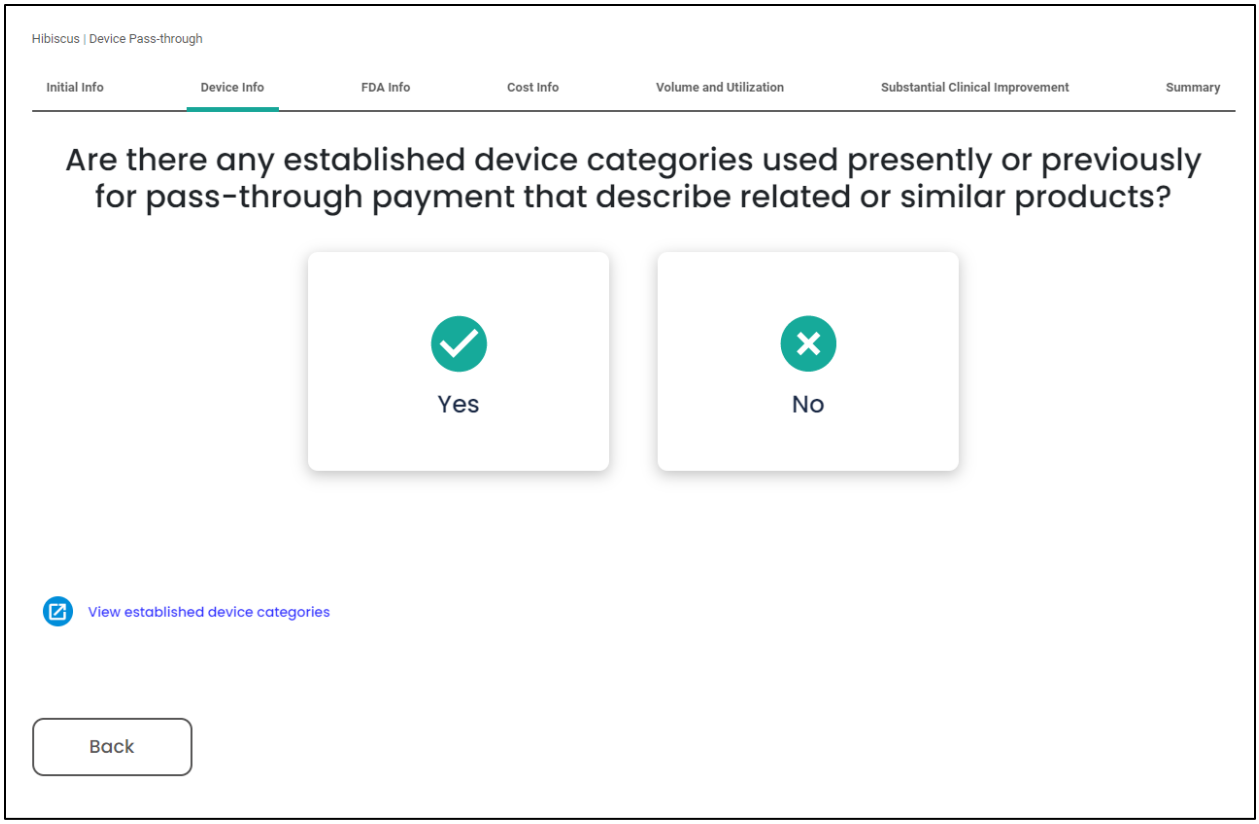
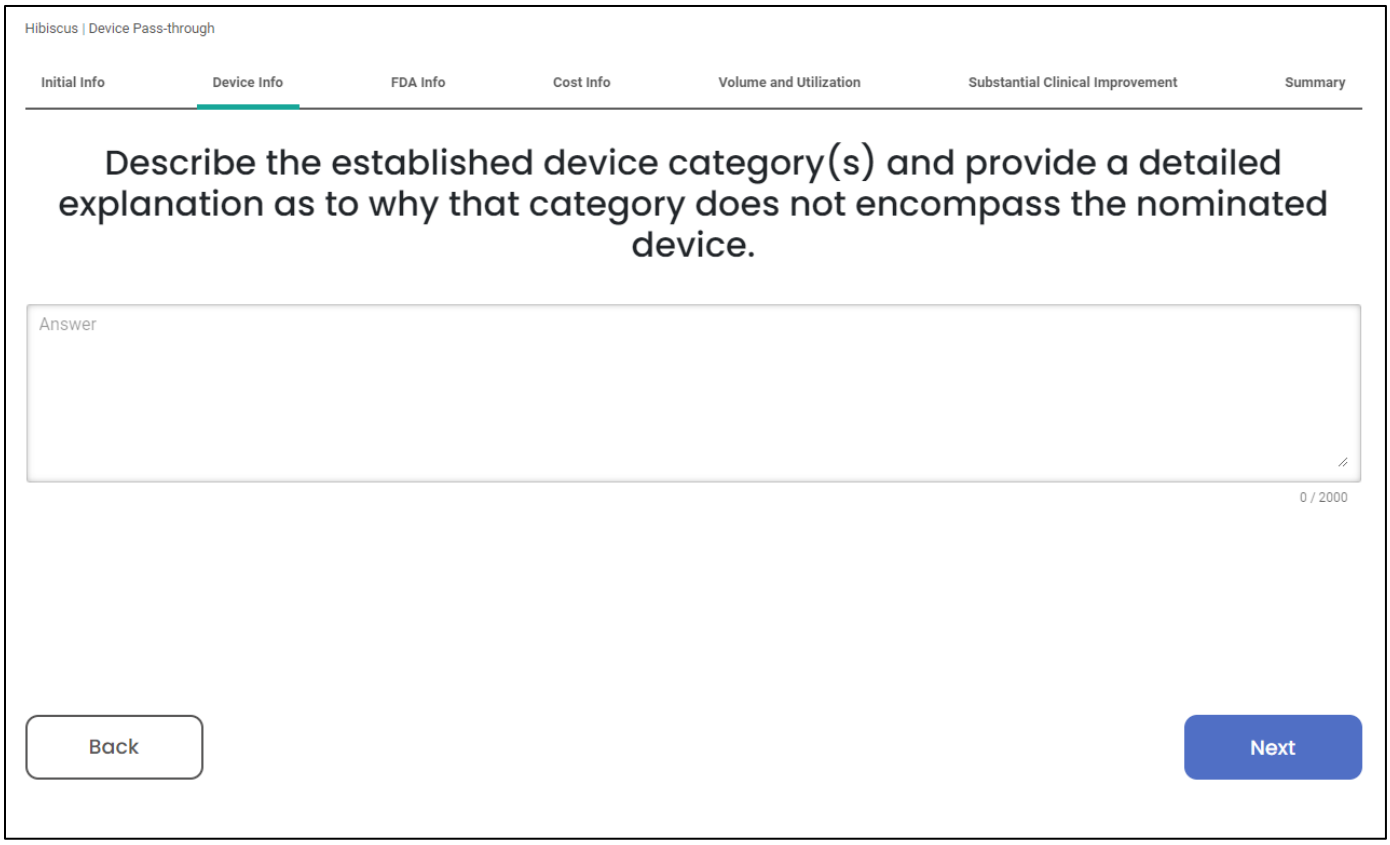
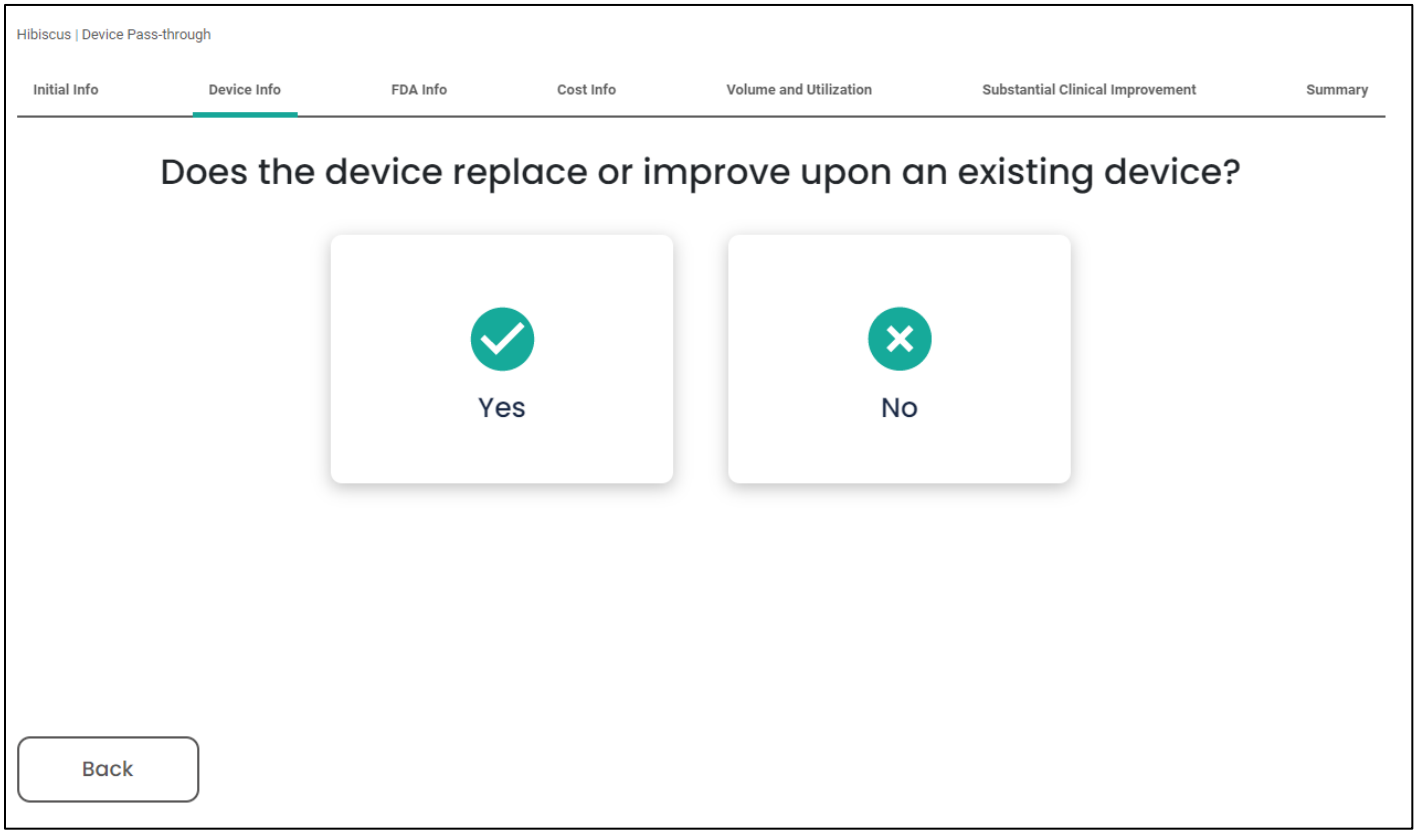
Summary
Using Healthcare Common Procedure Coding System (HCPCS) Level 1 and/or Level II code(s), list all of the specific procedure(s) and/or services with which the nominated device is used.
Enter HCPCS codes and titles
HCPCS General Info
Back
Next


Hibiscus | Device Pass-through
Initial Info
Device Info
FDA Info
Cost Info
Volume and Utilization
Substantial Clinical Improvement
Summary
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
Back

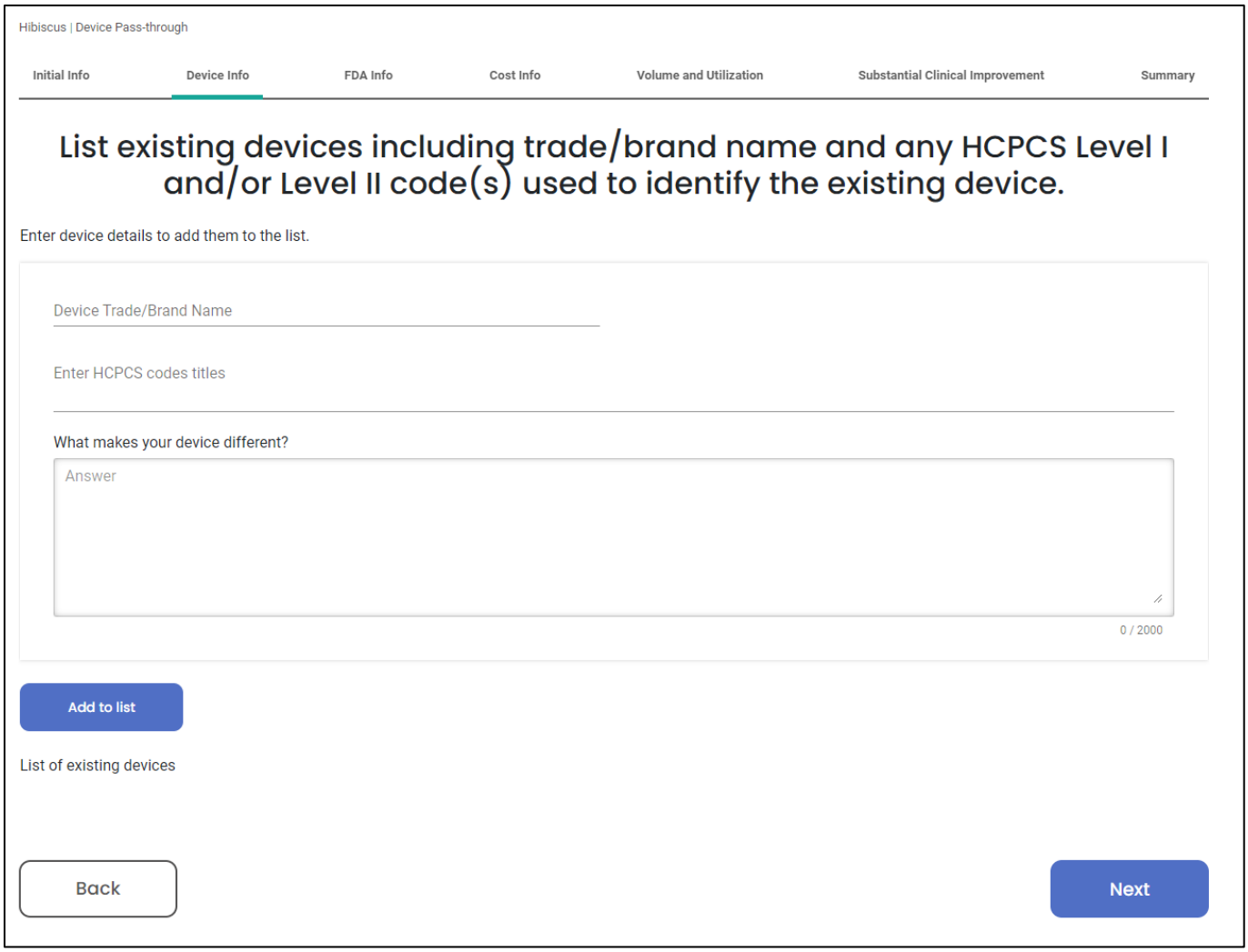
Clicking “Yes” takes you to this page:

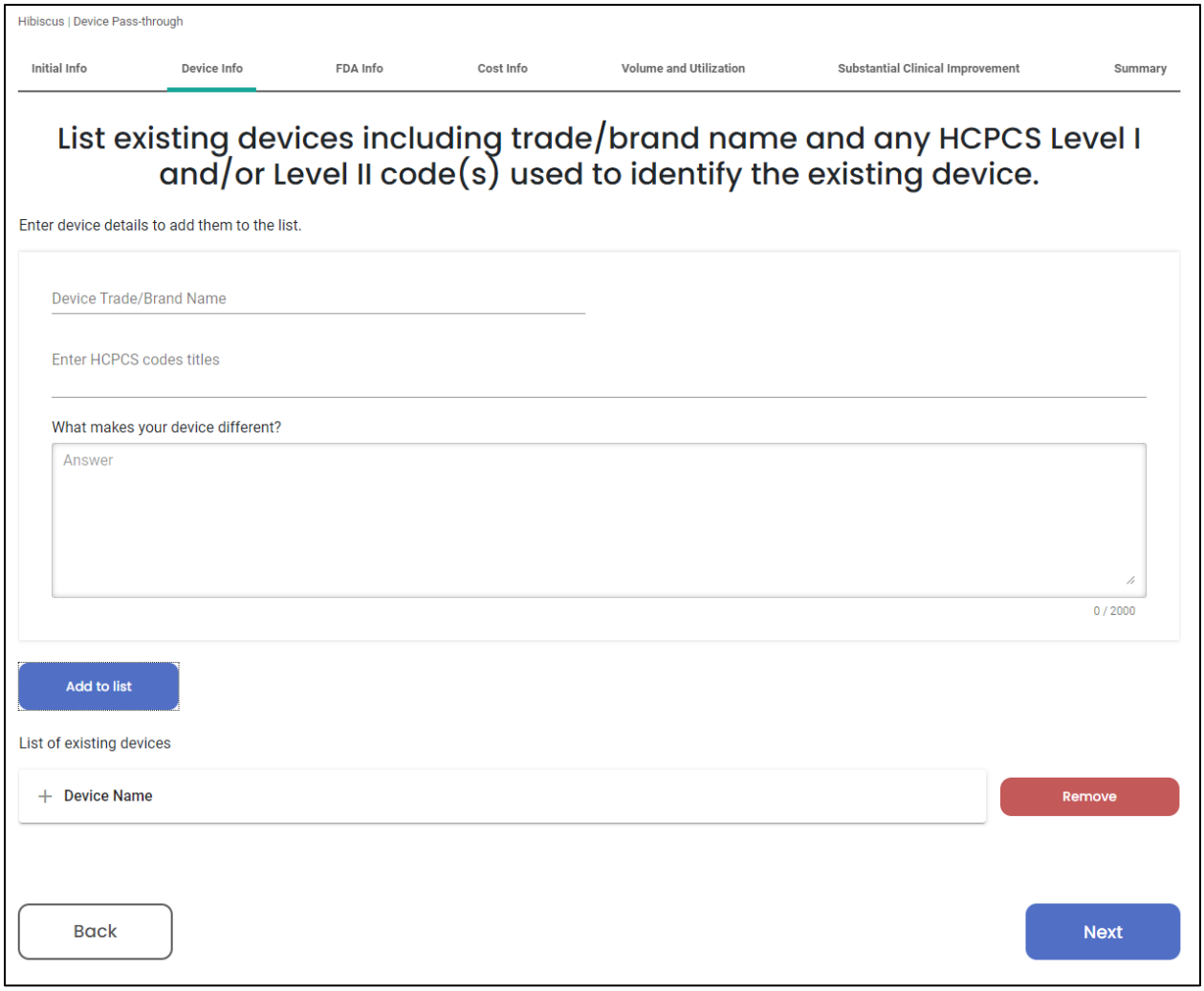


Clicking “No” takes you to this page:

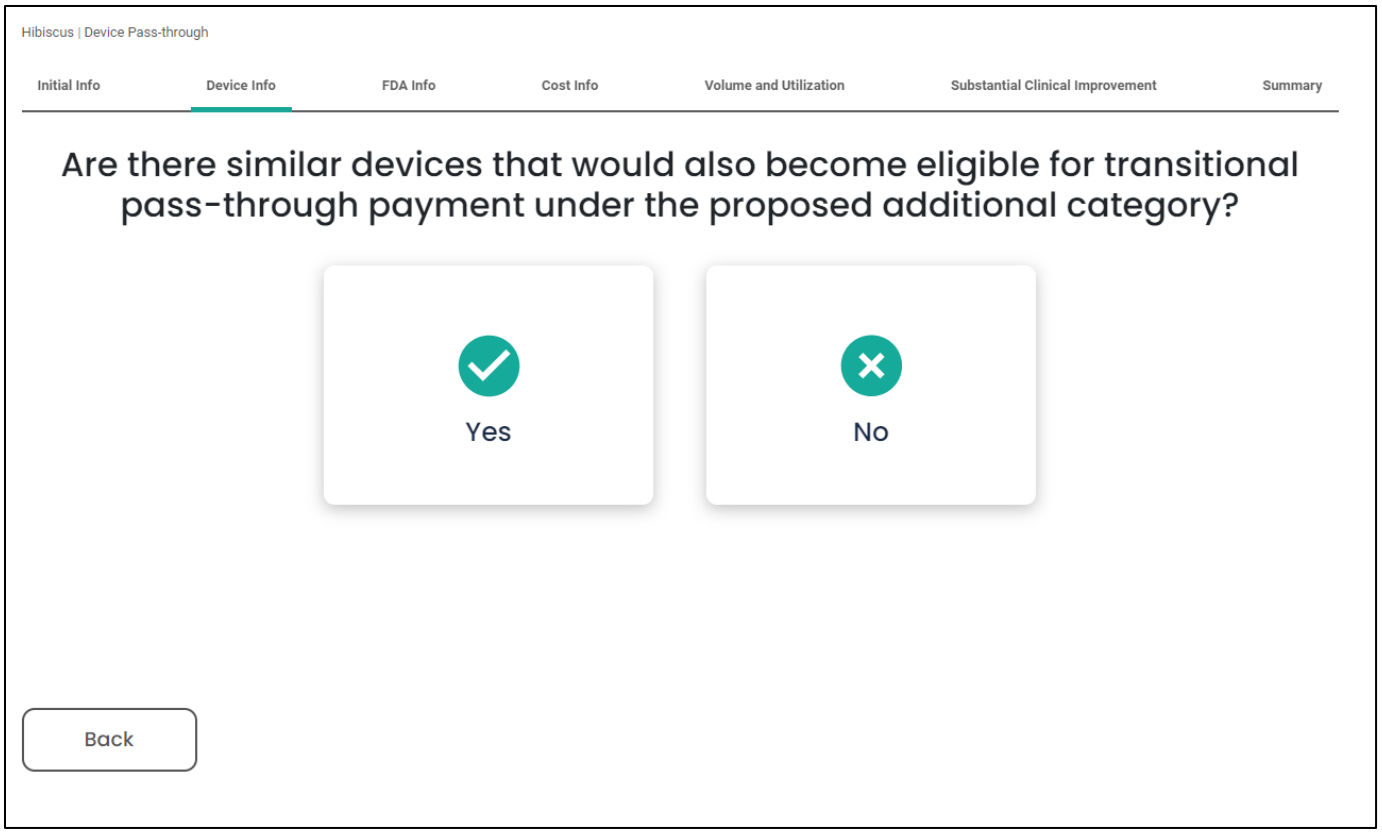


Clicking “Yes” takes you here:

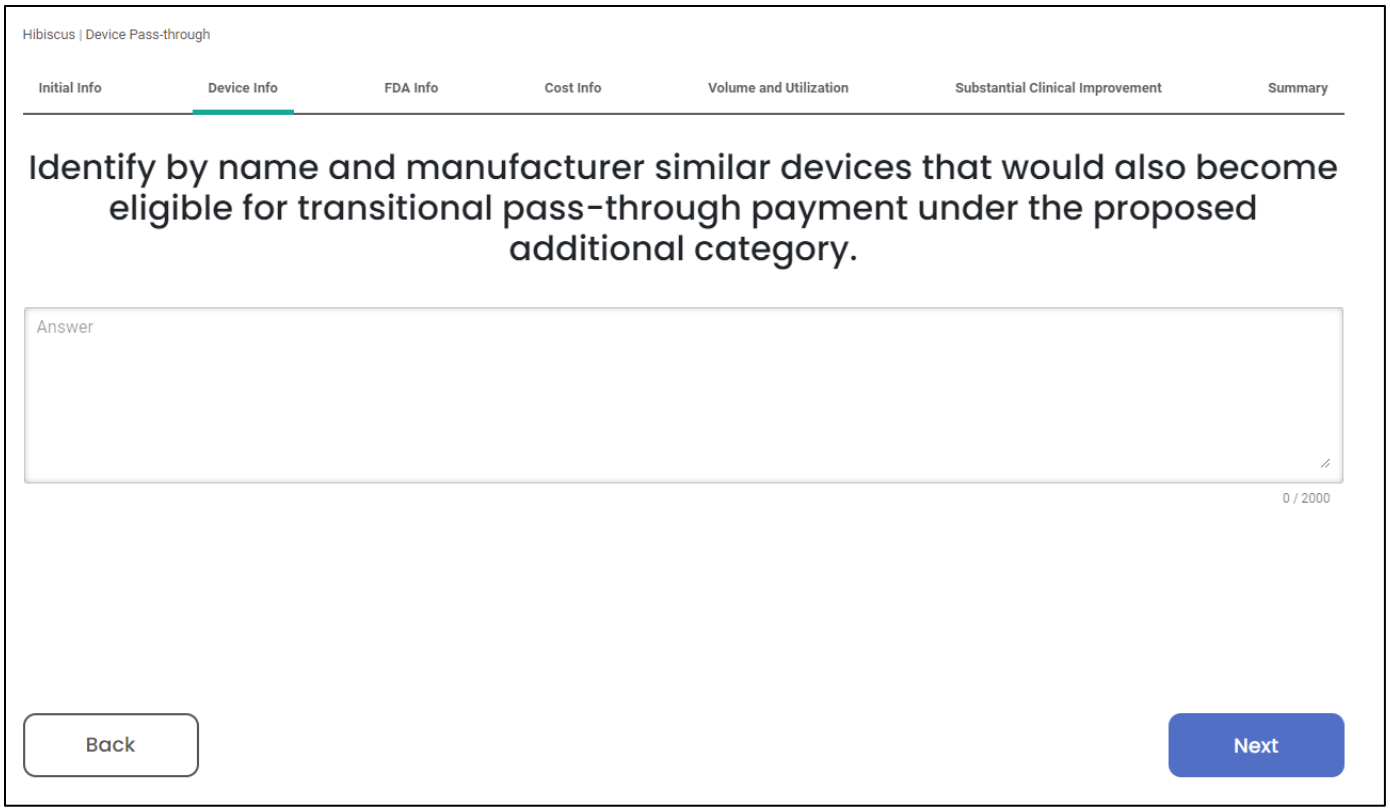



Hibiscus | Device Pass-through
Initial Info
Device Info
FDA Info
Cost Info
Volume and Utilization
Substantial Clinical Improvement
Summary
List existing devices including trade/brand name and any HCPCS Level I and/or Level II code(s) used to identify the existing device.
Enter device details to add them 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
Back
Next

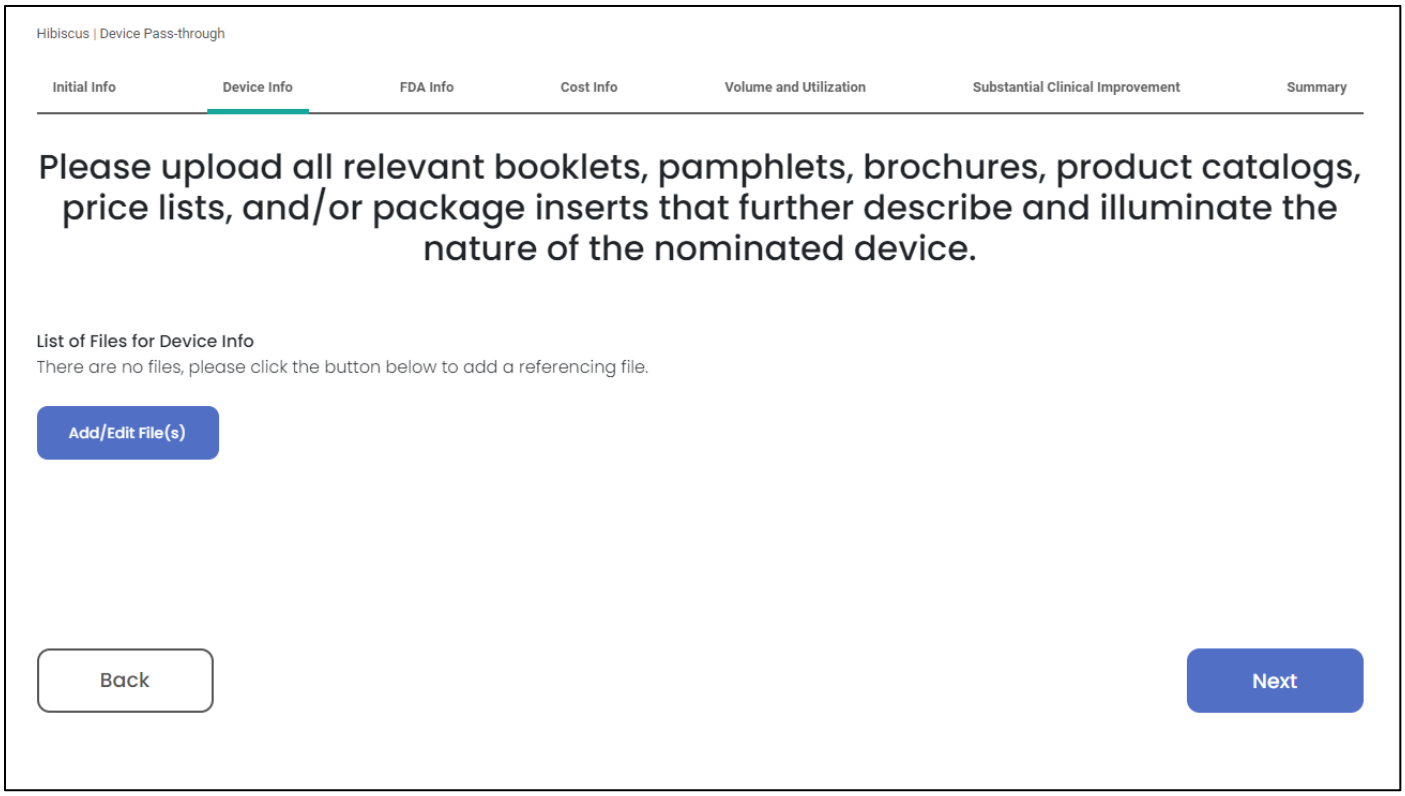
Clicking “No” takes you here:



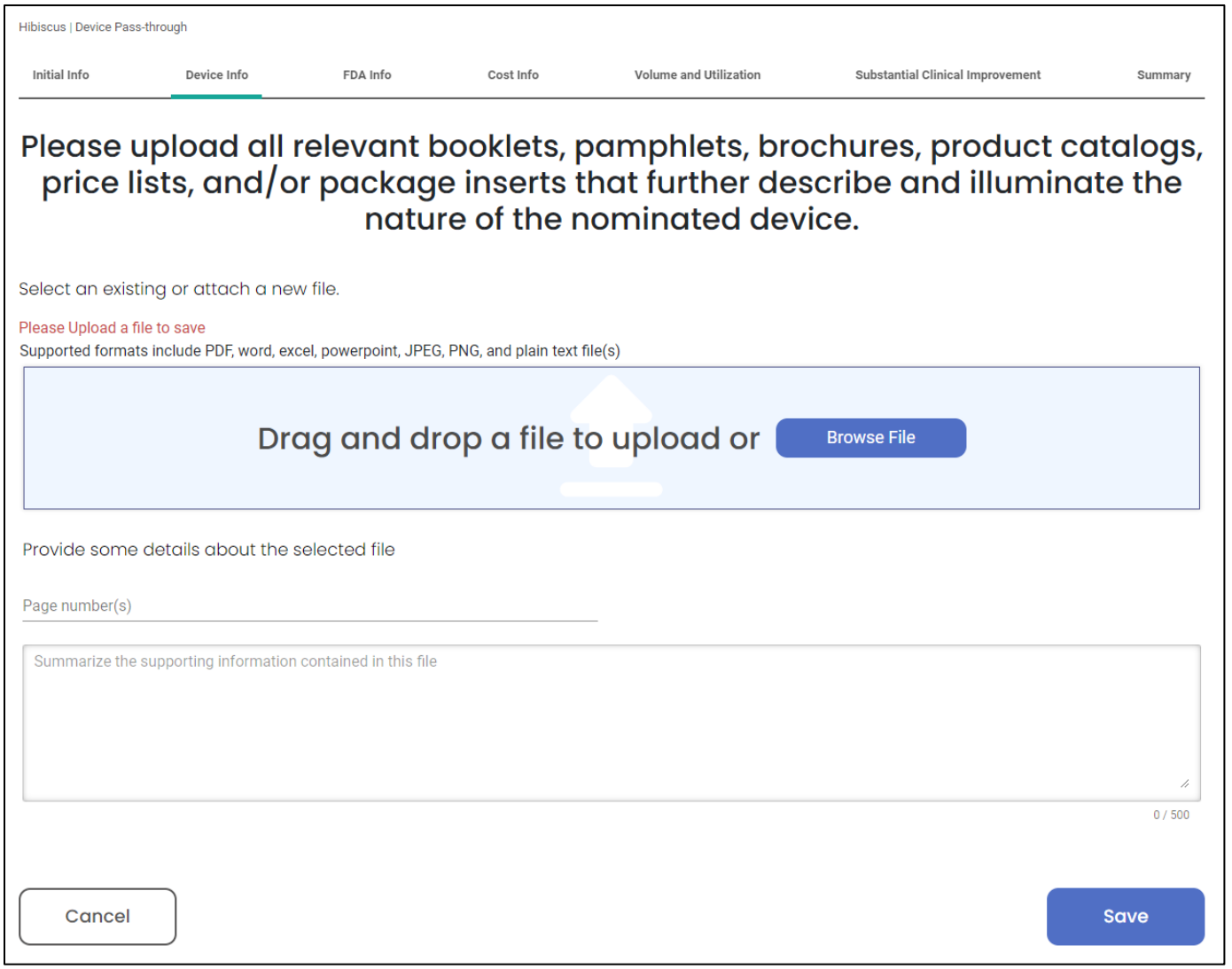
Clicking “Yes” to the above screen takes you here:



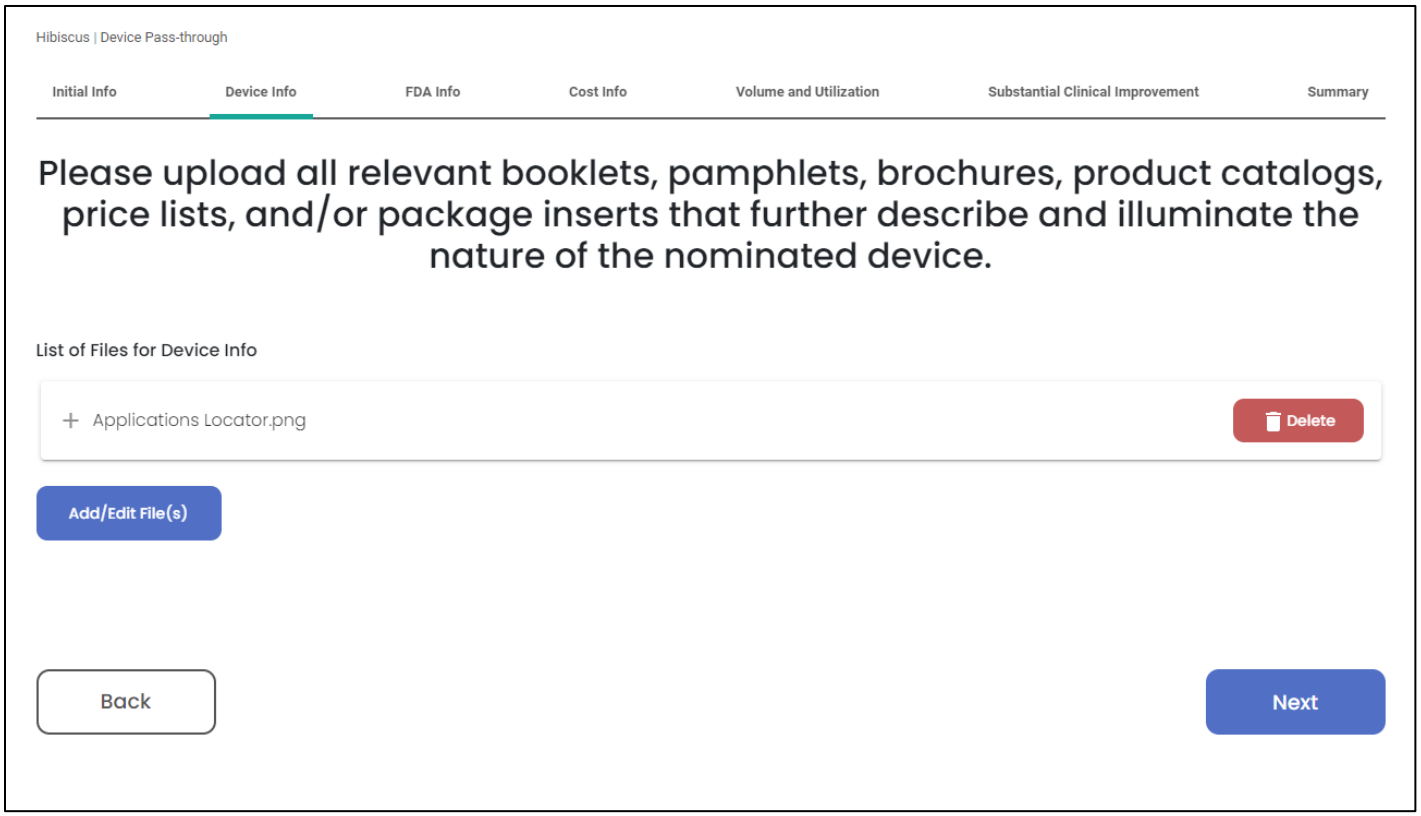
Clicking “No” takes you here:

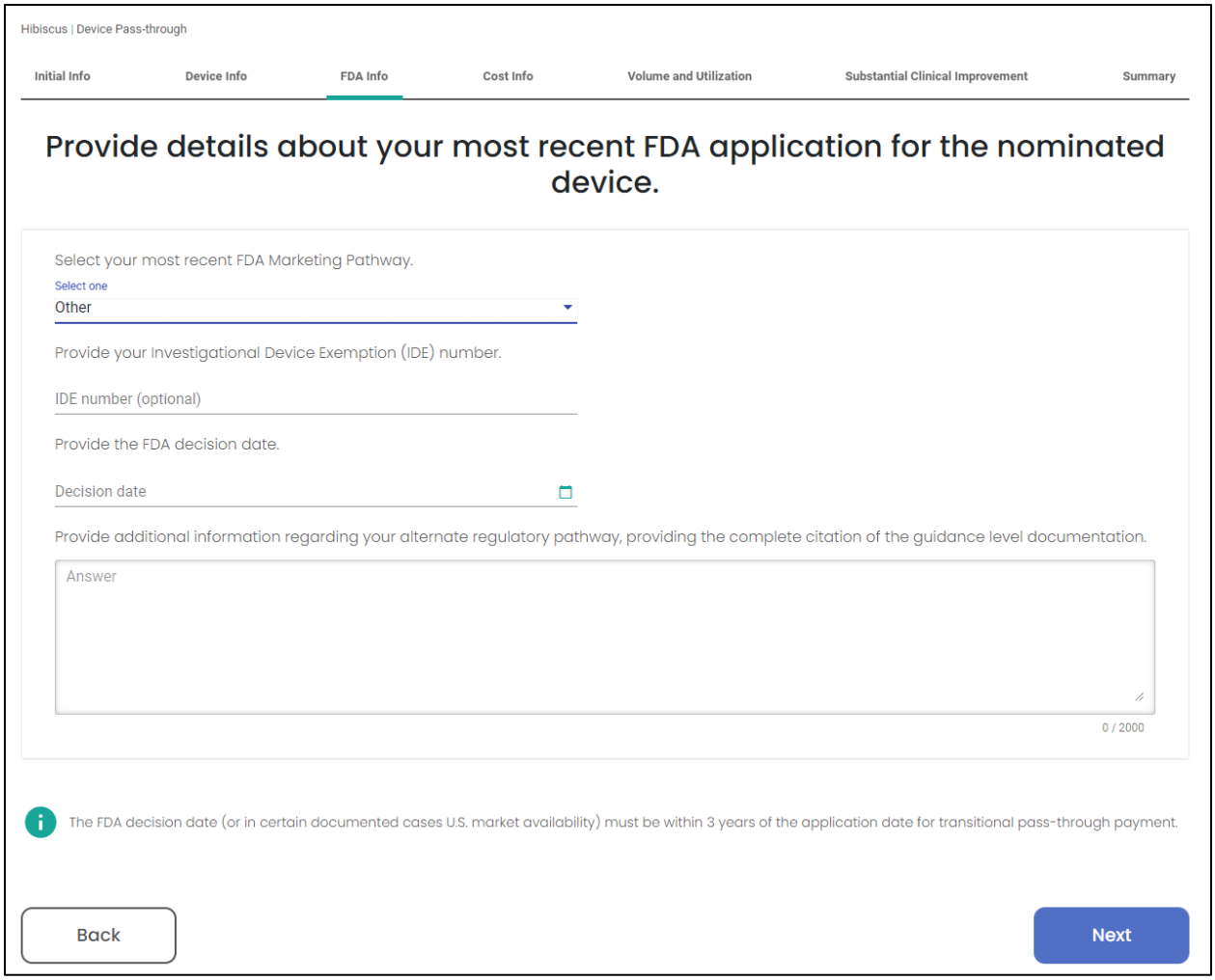


Clicking on “Add/Edit File(s)” takes you to this screen:



Clicking “Save” takes you to this screen:




Hibiscus | Device Pass-through
Initial Info
Device Info
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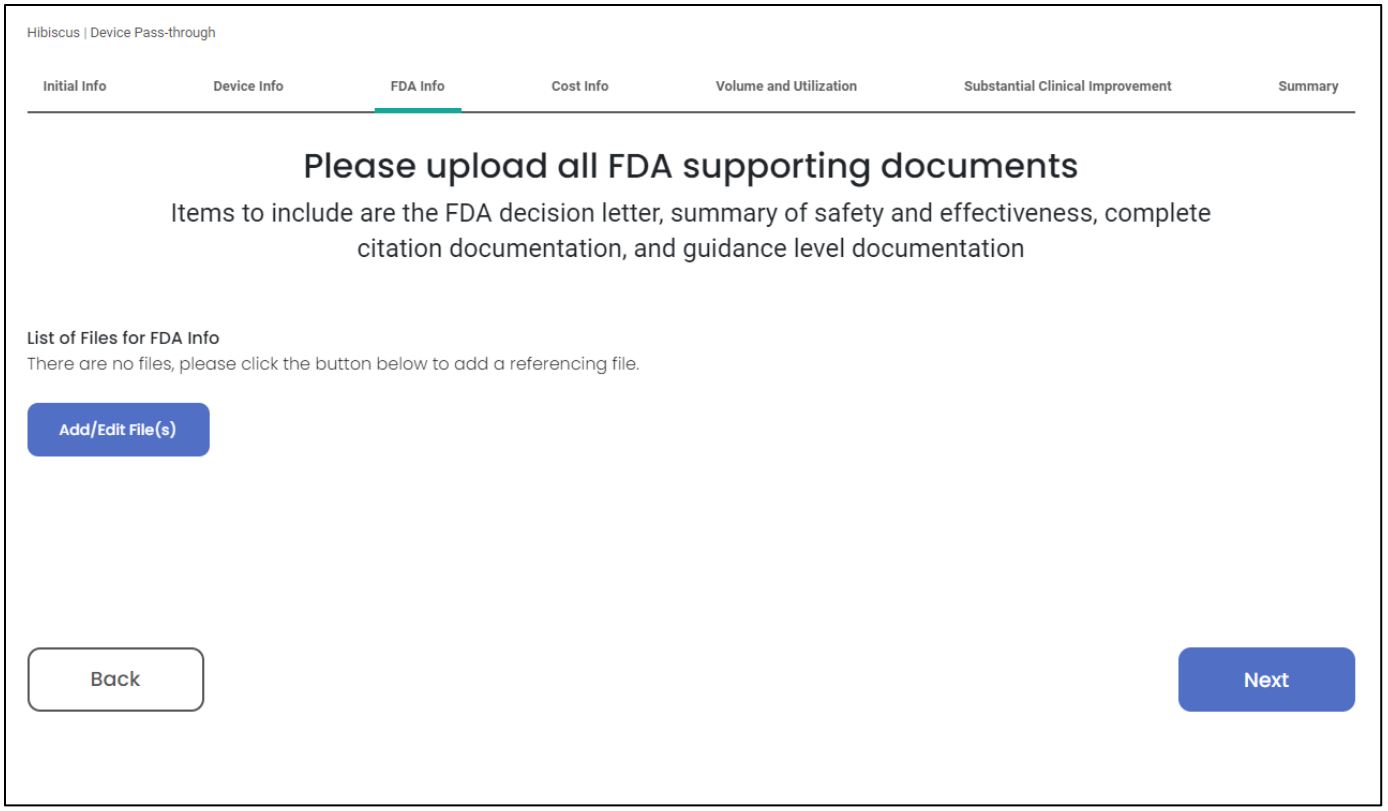
Cost Info
Volume and Utilization
Substantial Clinical Improvement
Summary
Provide details about your most recent FDA application for the nominated device.
Select your most recent FDA Marketing Pathway.
Select one
Other
Provide your Investigational Device Exemption (IDE) number.
IDE number (optional)
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.
Back
Next


Hibiscus | Device Pass-through
Initial Info
Device Info
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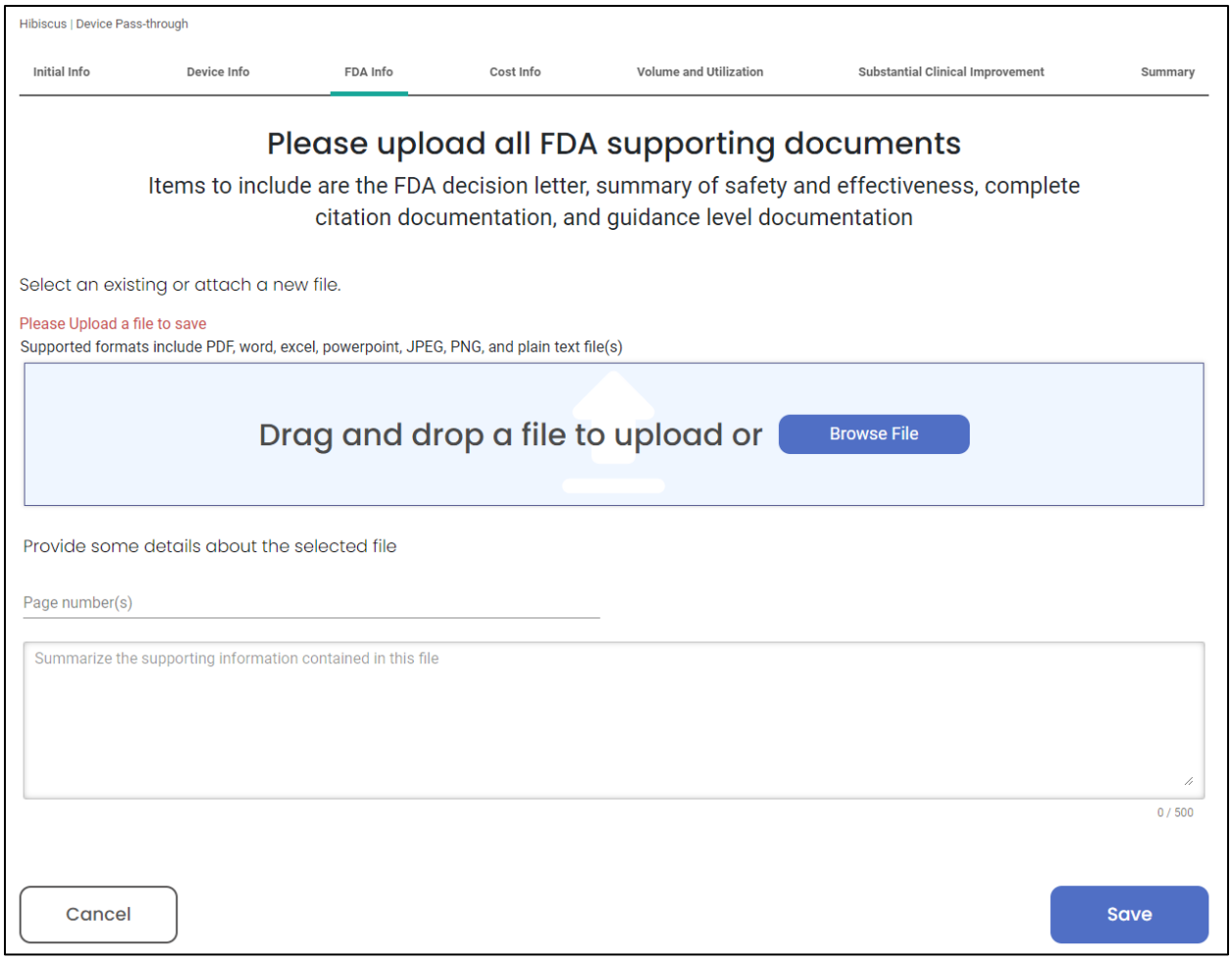
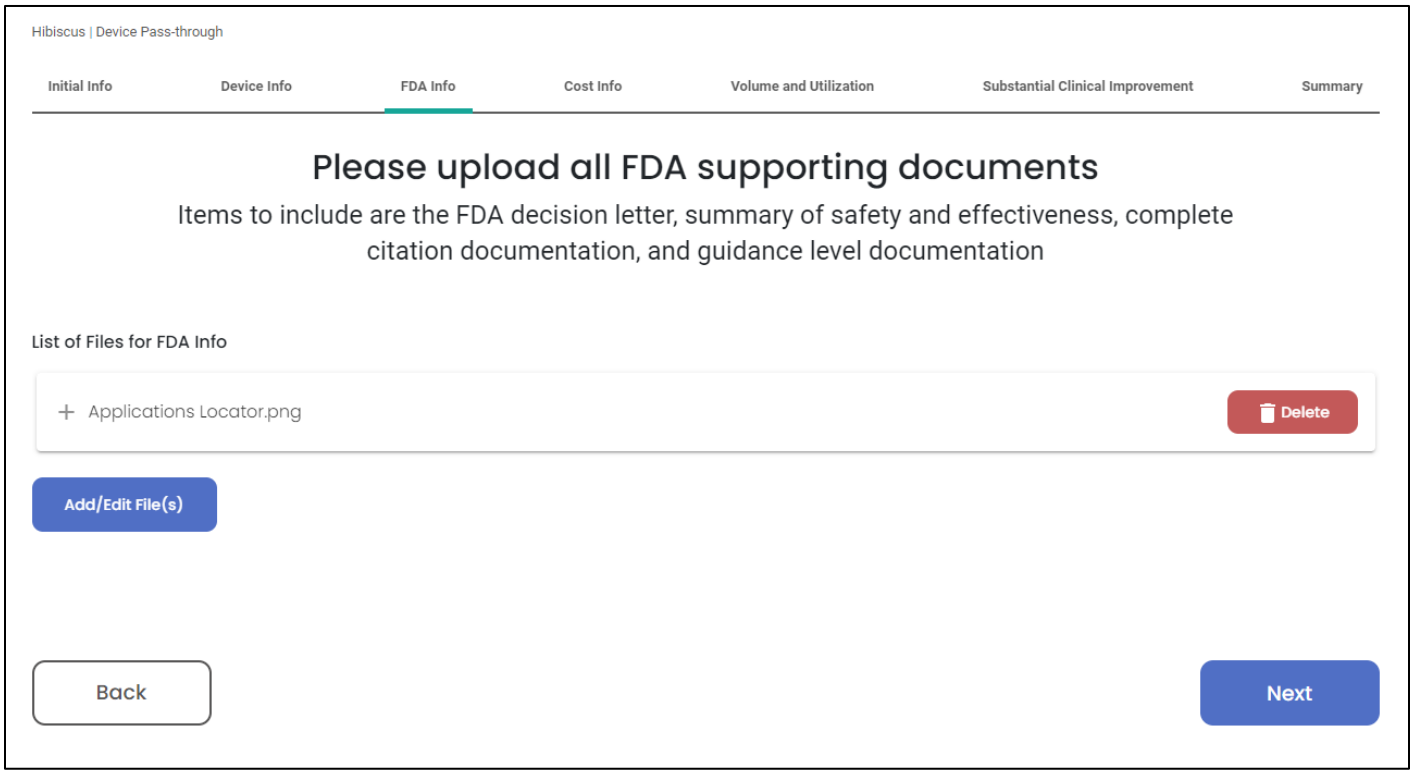
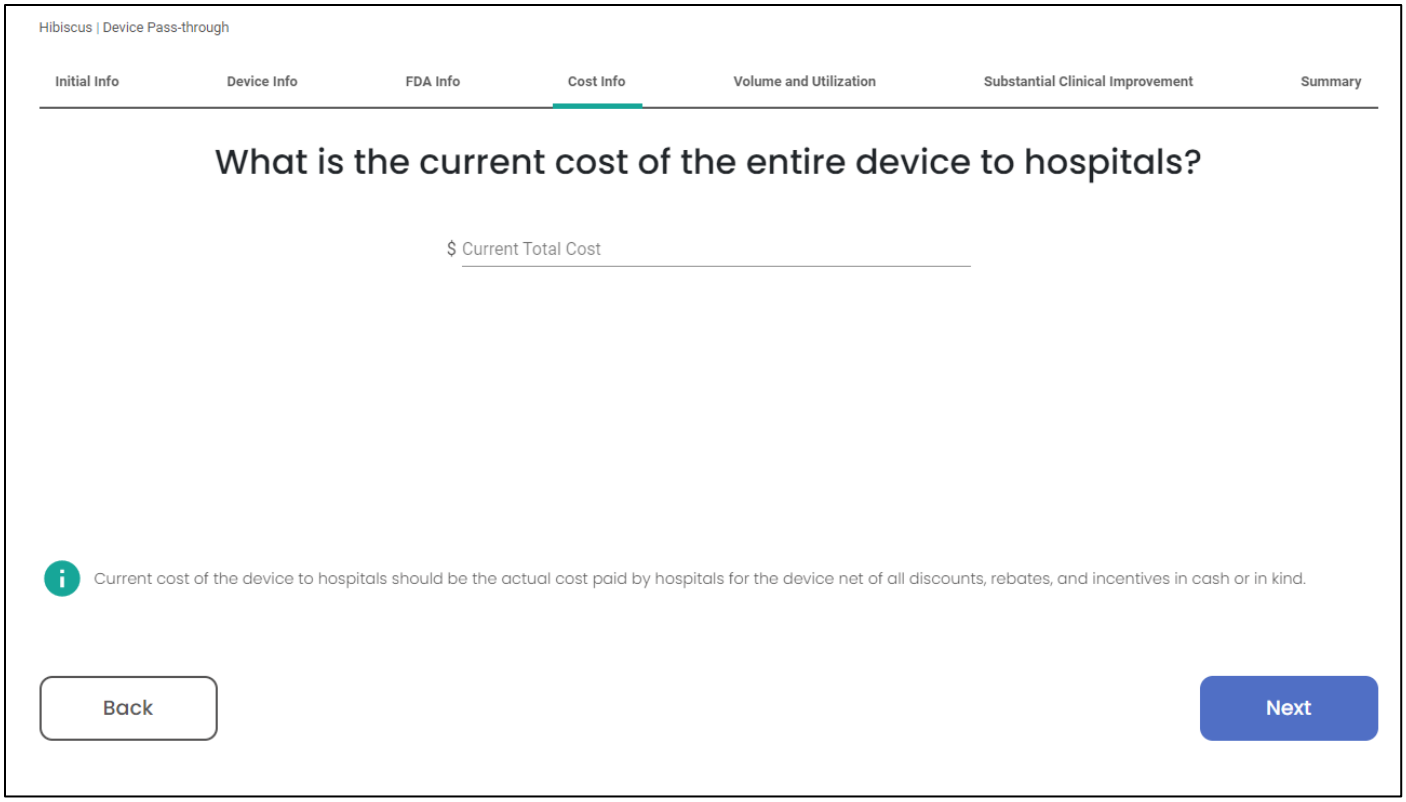
Substantial Clinical Improvement
Summary
Please upload all FDA supporting documents
Items to include are the FDA decision letter, summary of safety and effectiveness, complete citation documentation, and guidance level documentation
List of Files for FDA Info
There are no files, please click the button below to add a referencing file.
Add/Edit File(s)
Back
Next

Clicking on “Add/Edit File(s)” takes you to this screen:



Clicking “Save” will take you to this screen:




Hibiscus | Device Pass-through
Initial Info
Device Info
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Cost Info
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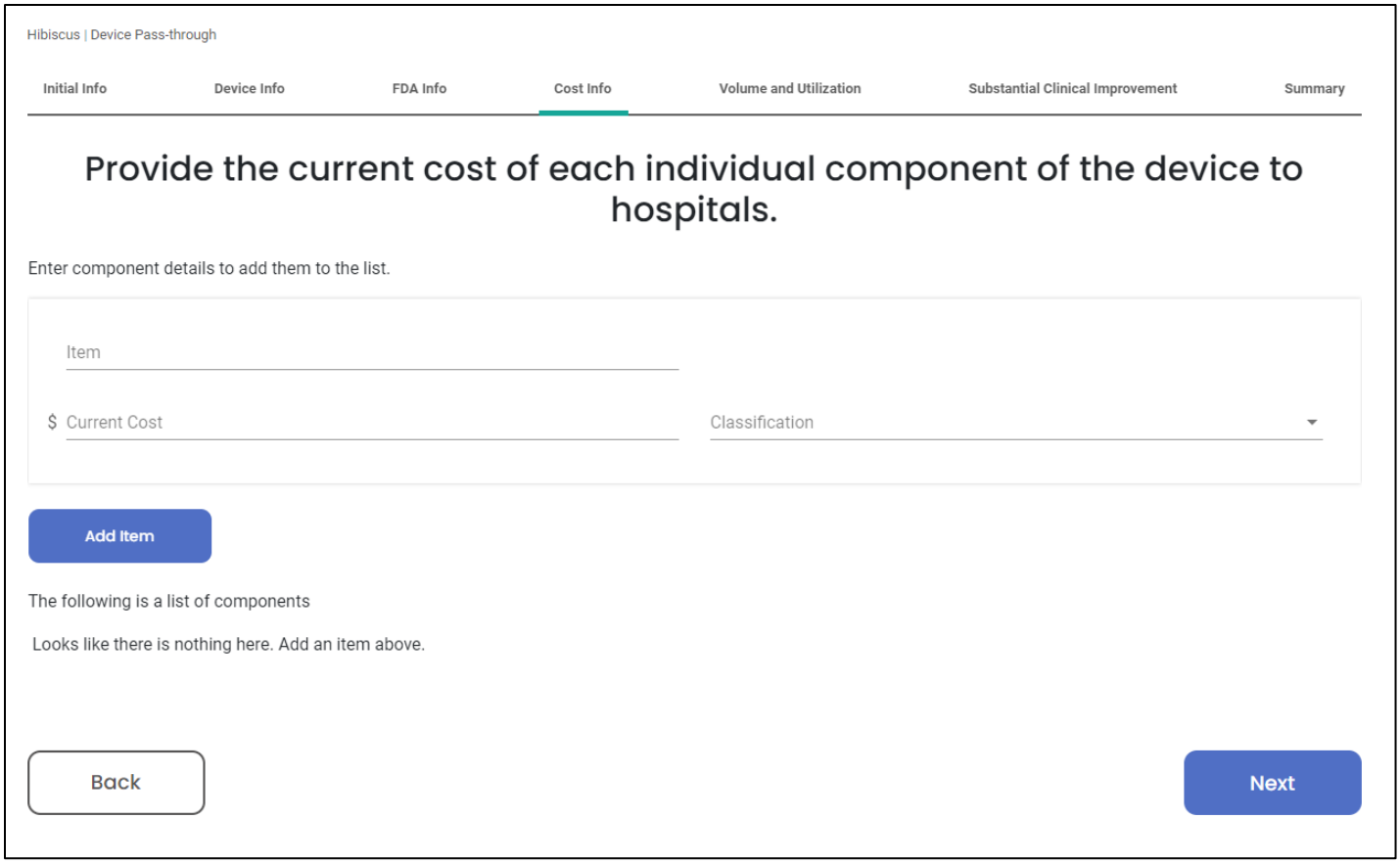
Substantial Clinical Improvement
Summary
What is the current cost of the entire device to hospitals?
$ Current Total Cost
Current cost of the device to hospitals should be the actual cost paid by hospitals for the device net of all discounts, rebates, and incentives in cash or in kind.
Back
Next


Hibiscus | Device Pass-through
Initial Info
Device Info
FDA Info
Cost Info
Volume and Utilization
Substantial Clinical Improvement
Summary
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.
Back
Next

Hibiscus | Device Pass-through

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

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

Summary (optional)

0 / 2000

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Hibiscus | Device Pass-through

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

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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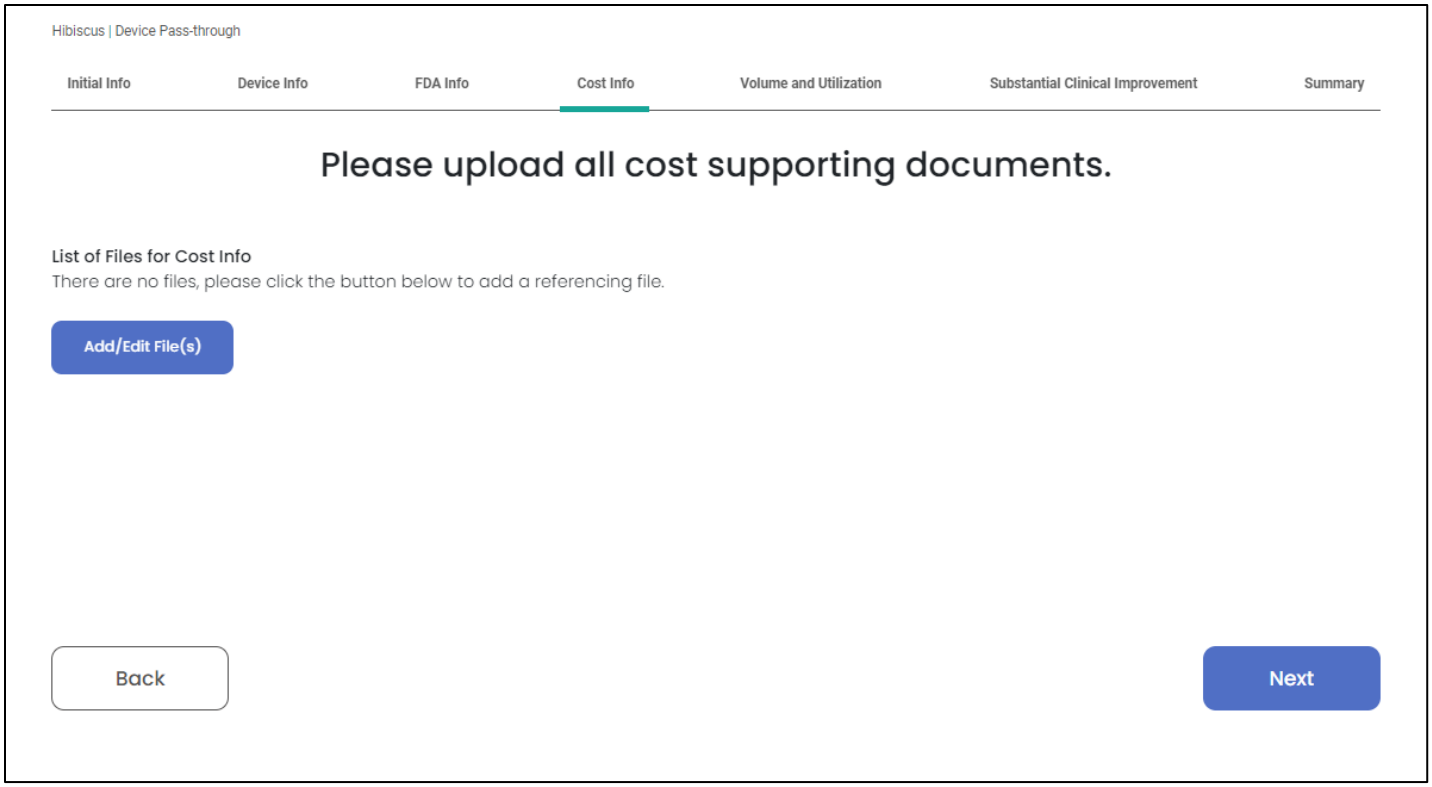
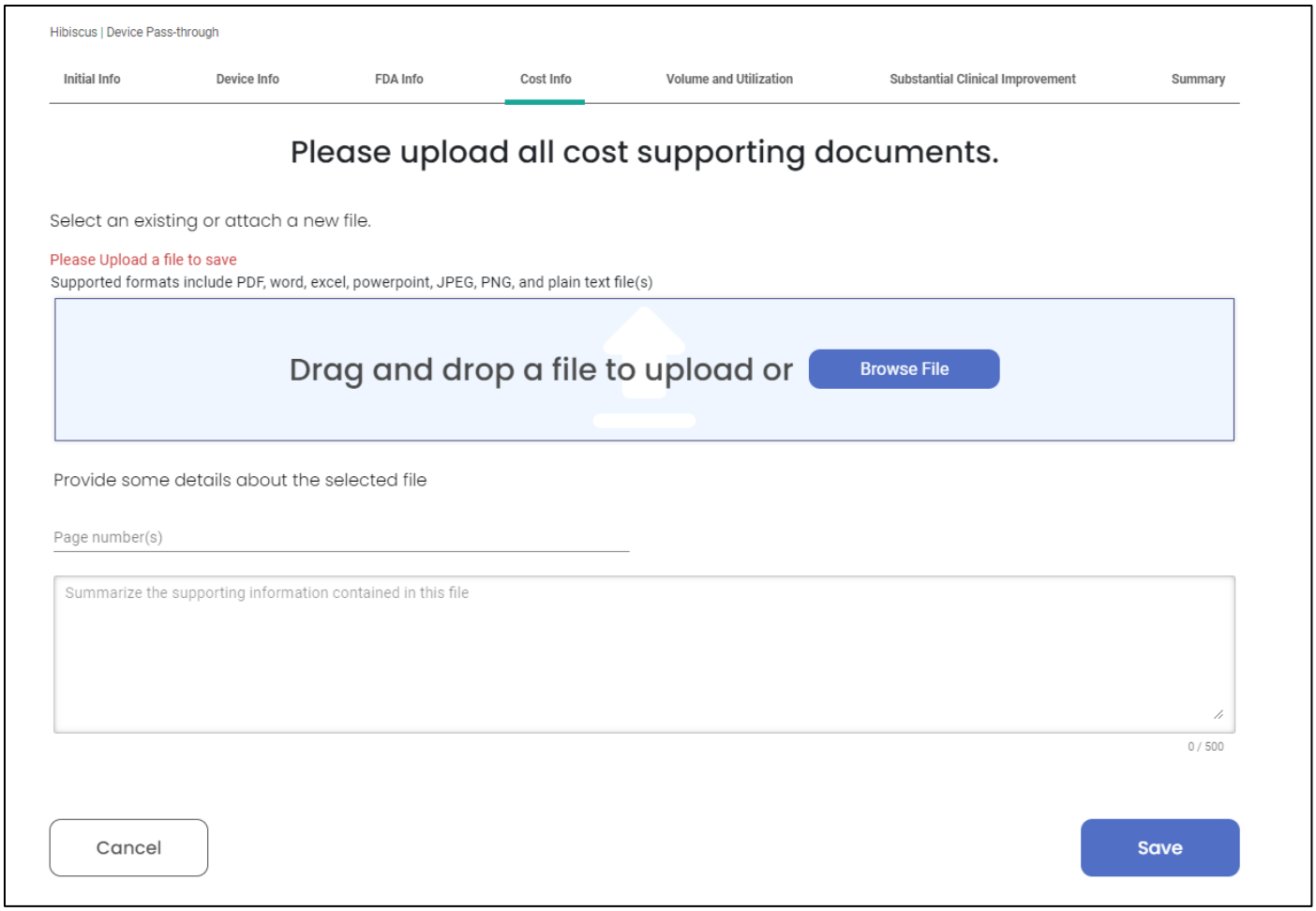
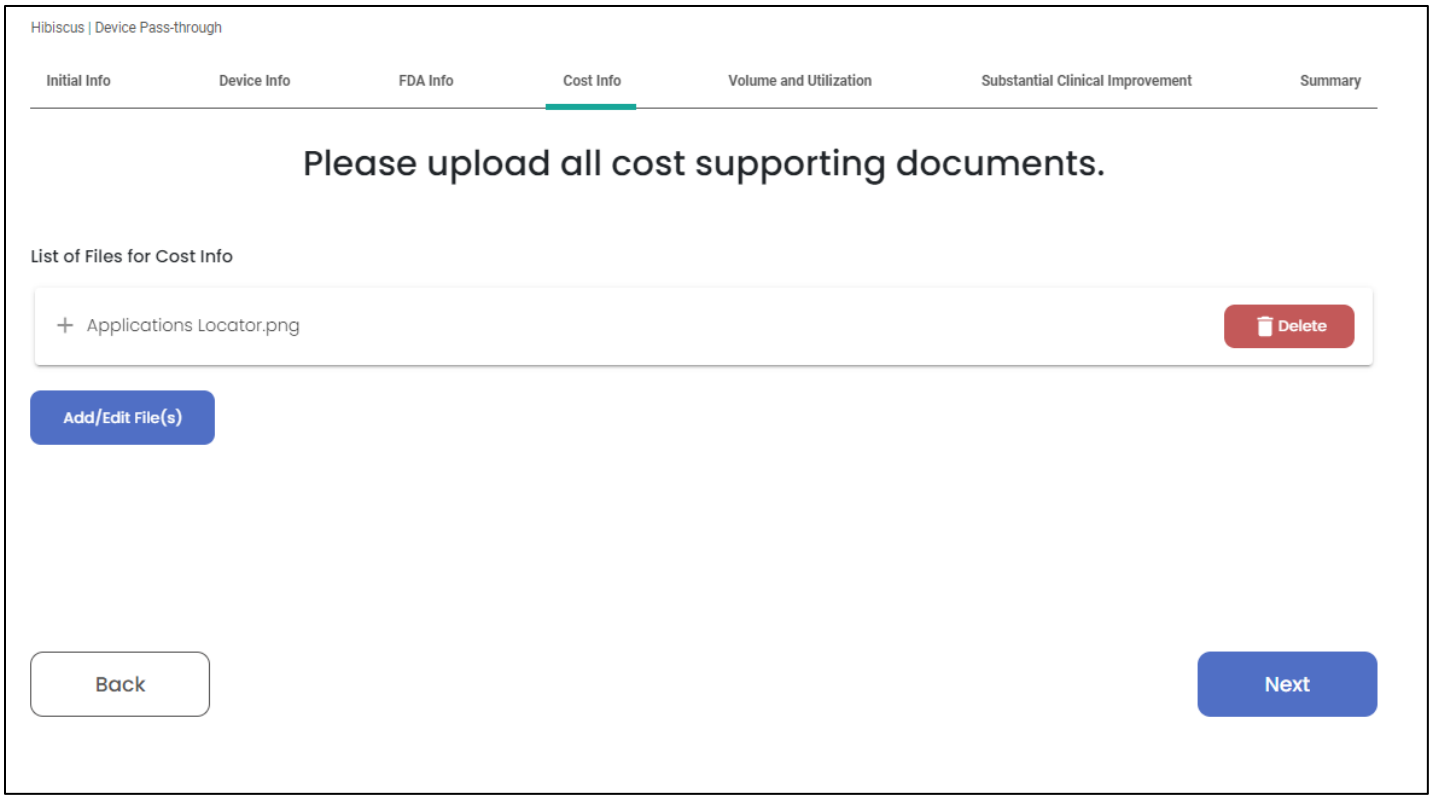

Hibiscus | Device Pass-through
Initial Info
Device Info
FDA Info
Cost Info
Volume and Utilization
Substantial Clinical Improvement
Summary
Please upload all cost supporting documents.
List of Files for Cost Info
There are no files, please click the button below to add a referencing file.
Add/Edit File(s)
Back
Next

Clicking “Add/Edit File(s)” will take you to this screen:



Clicking “Save” takes you to this screen:



Hibiscus | Device Pass-through

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

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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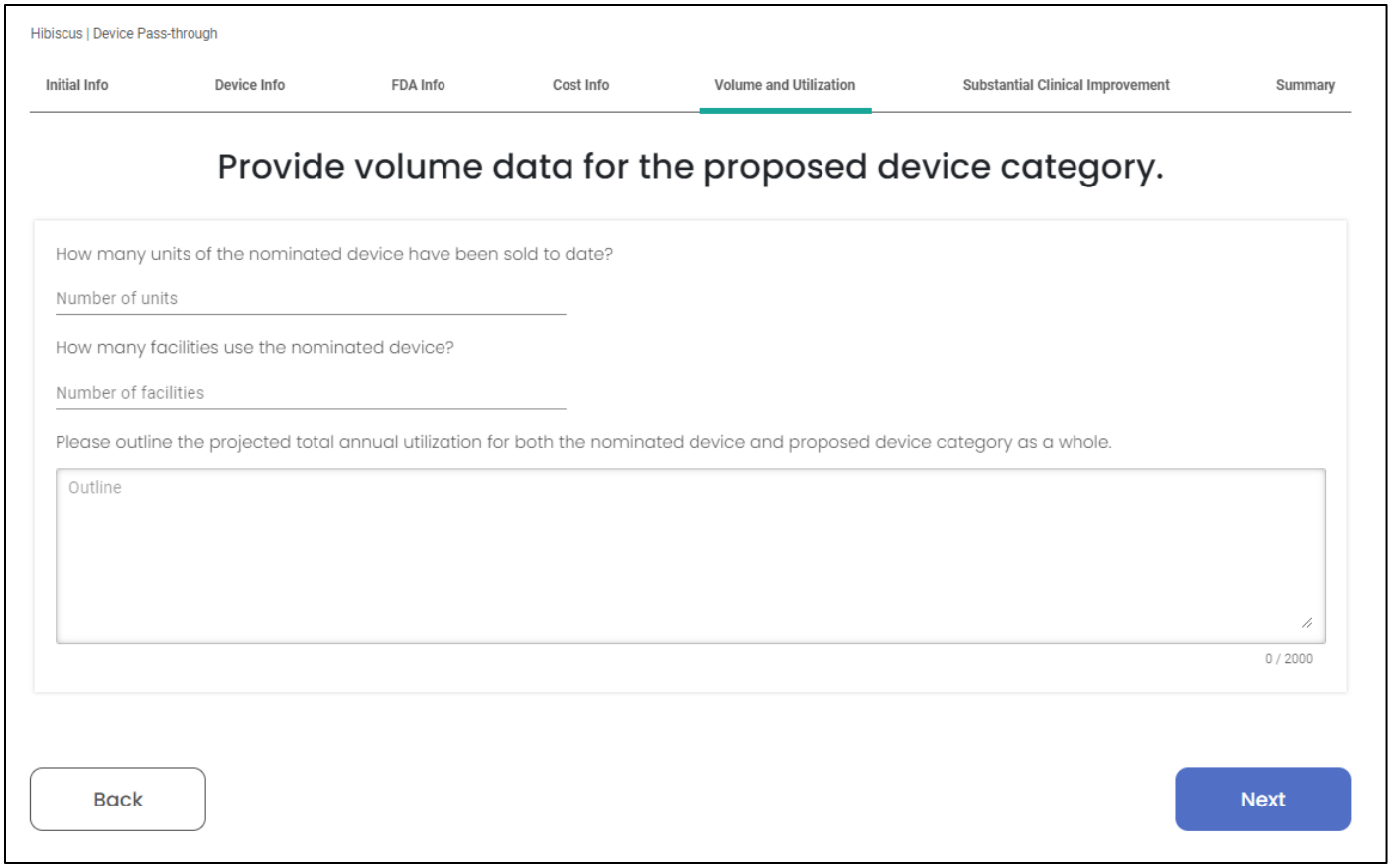
Next


Hibiscus | Device Pass-through
Initial Info
Device Info
FDA Info
Cost Info
Volume and Utilization
Substantial Clinical Improvement
Summary
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
0 / 2000
Back
Next

Hibiscus | Device Pass-through

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

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

12

Ambulatory Surgical Center

12

Hospital Inpatient

12

Physician Office

12

Other (optional)

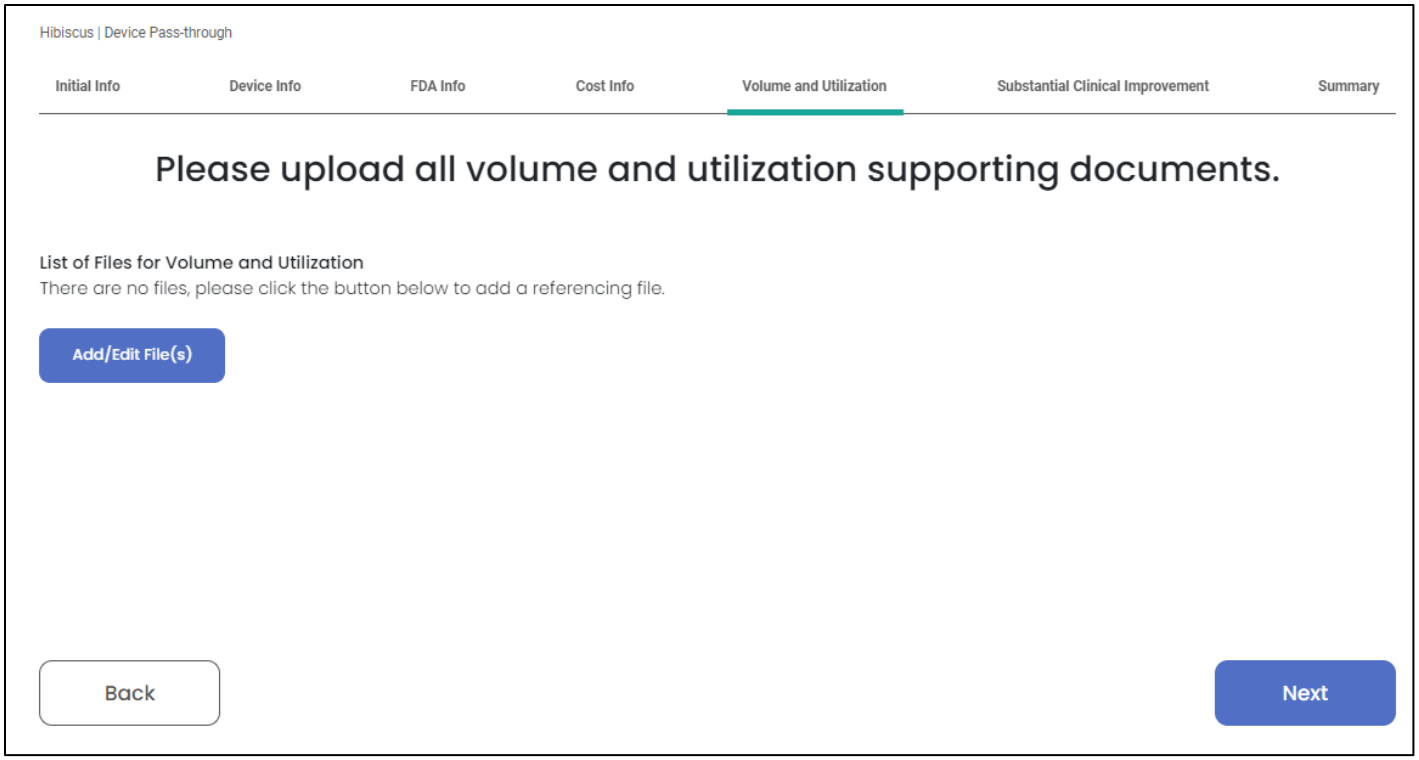
12

Define what the "Other" utilization category is

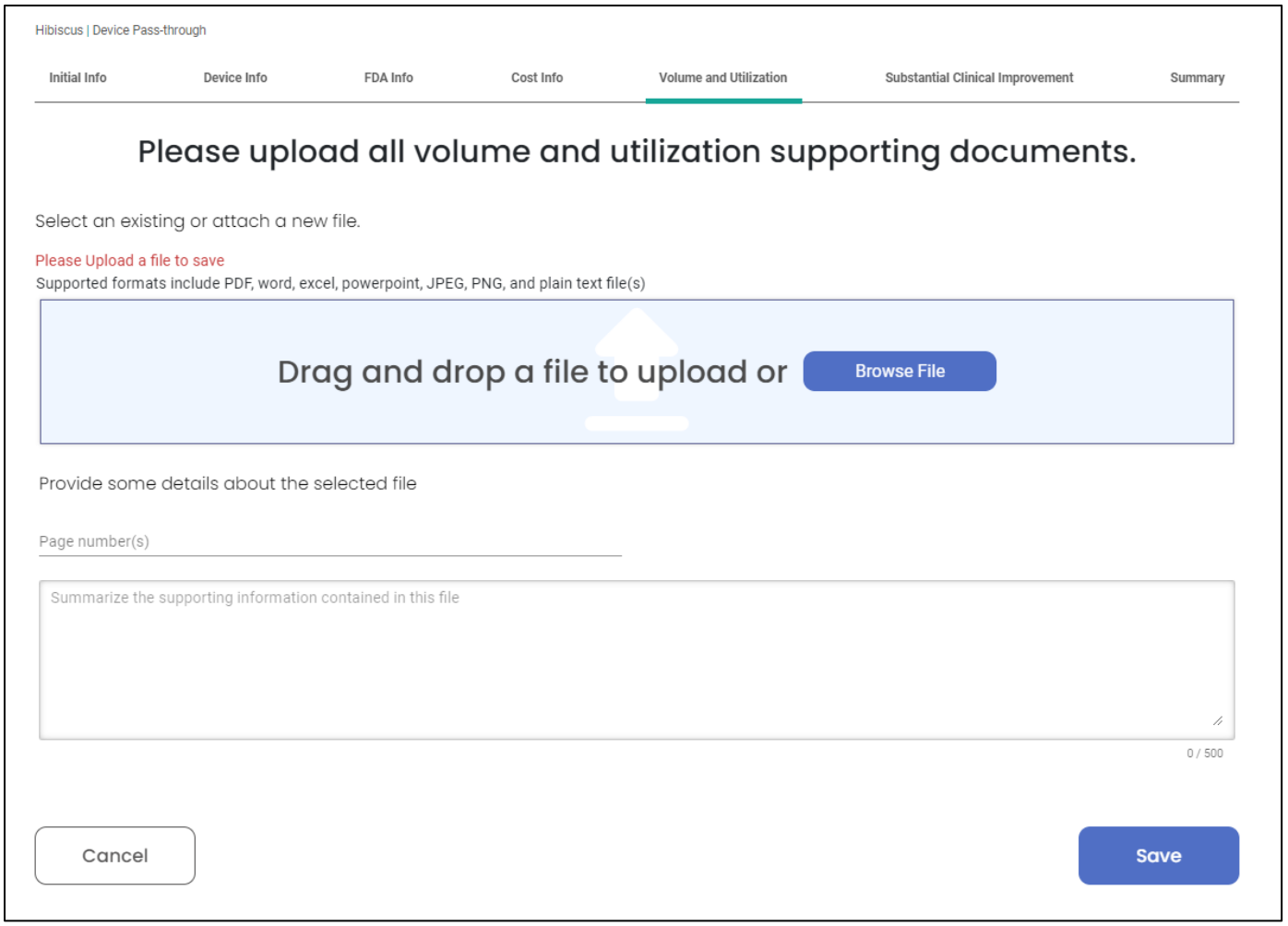
Explanation

Back

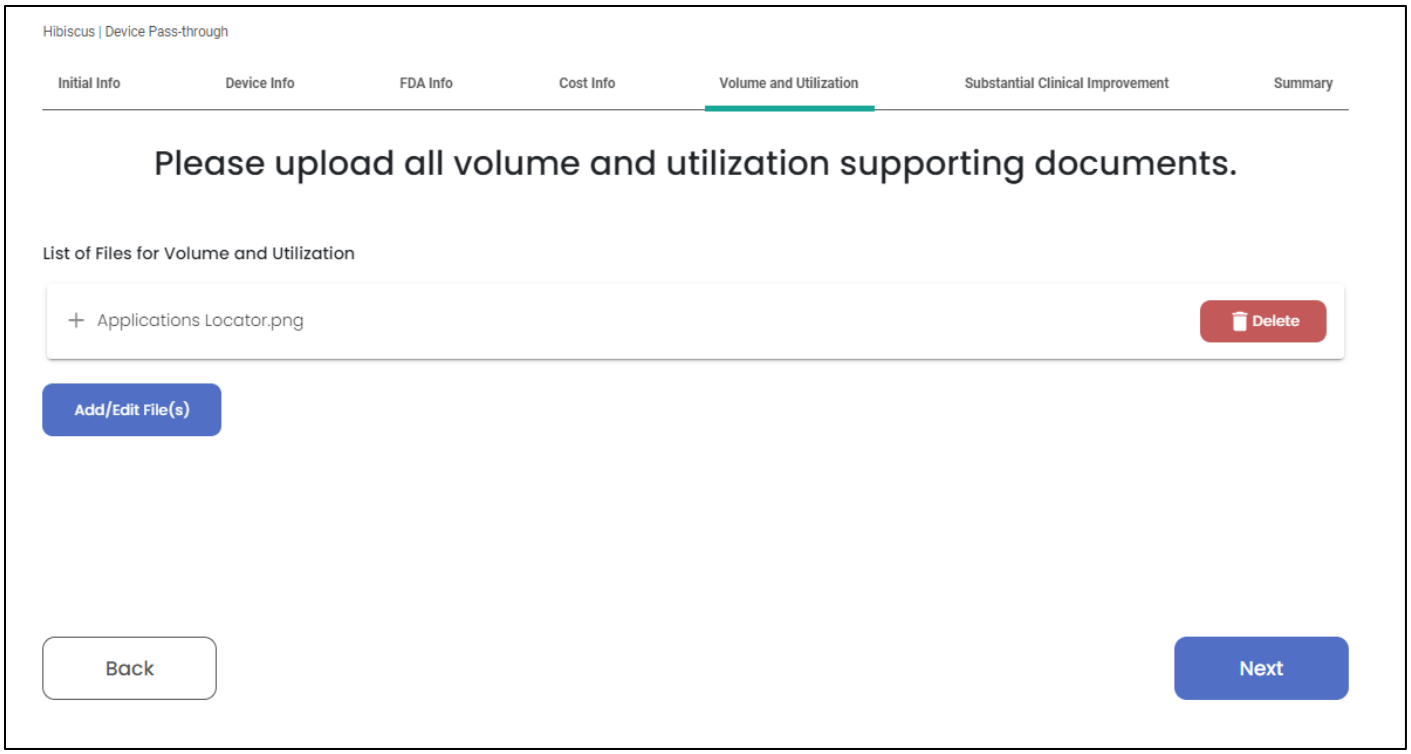
Next

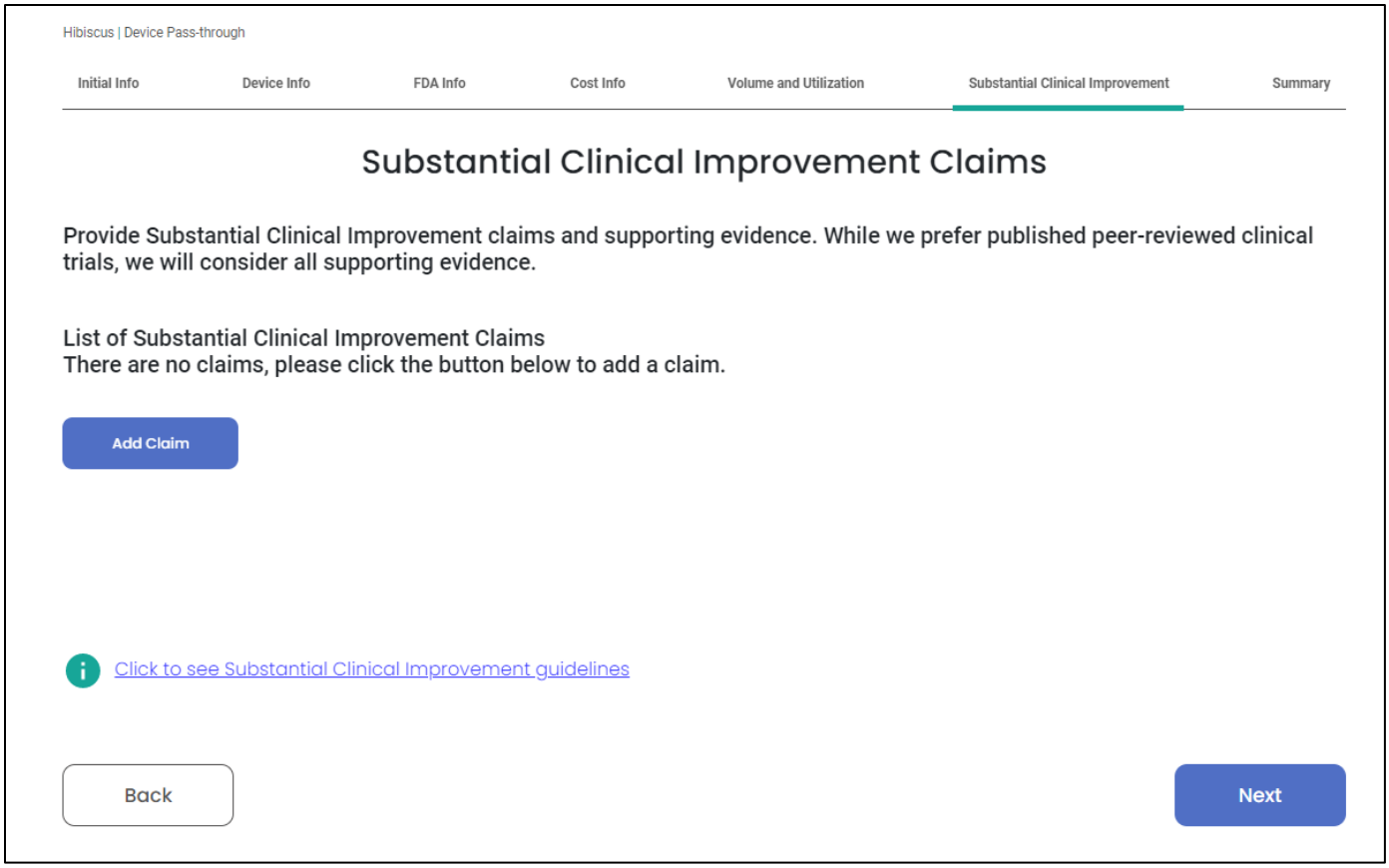

Hibiscus | Device Pass-through
Initial Info
Device Info
FDA Info
Cost Info
Volume and Utilization
Substantial Clinical Improvement
Summary
Please upload all volume and utilization supporting documents.
List of Files for Volume and Utilization
There are no files, please click the button below to add a referencing file.
Add/Edit File(s)
Back
Next

Clicking on “Add/Edit File(s)” takes you to this screen:



Clicking on “Save” will take you to this screen:




Hibiscus | Device Pass-through
Initial Info
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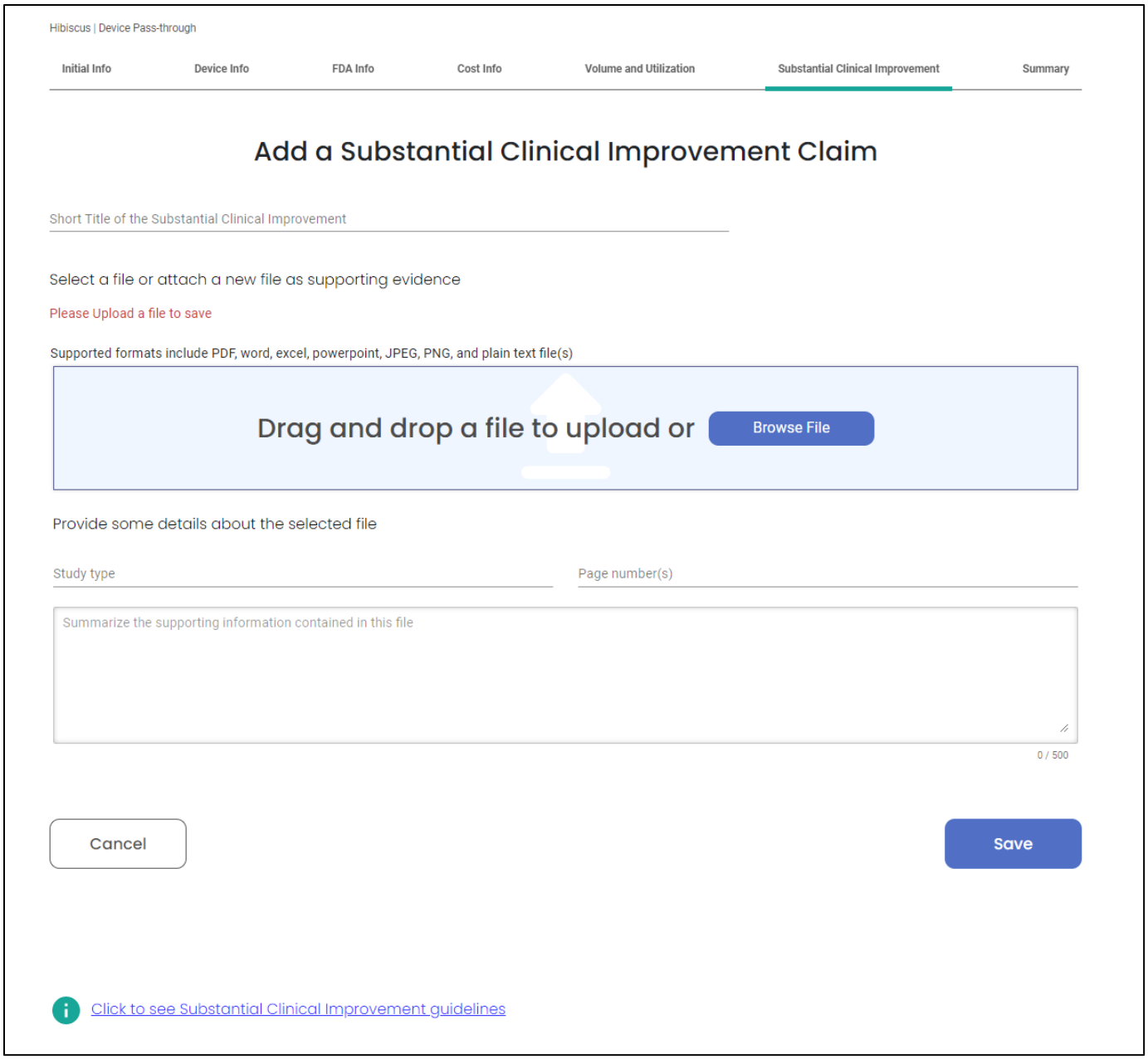
Summary
Substantial Clinical Improvement Claims
Provide Substantial Clinical Improvement claims and supporting evidence. While we prefer published peer-reviewed clinical trials, we will consider all supporting evidence.
List of Substantial Clinical Improvement Claims
There are no claims, please click the button below to add a claim.
Add Claim
Click to see Substantial Clinical Improvement guidelines
Back
Next

Clicking on “Add Claim” takes you to this screen:



Clicking “Save” will take you to this screen: