

Using the US Regulatory Calculator

- From the Analyze Page, select US Regulatory Calculator (see Figure 22a) to navigate to the Calculator Main Page (see Figure 22b). On this page the user should create a name and a brief, non-confidential description of the technology. When finished, select Next to proceed.

Figure 22a

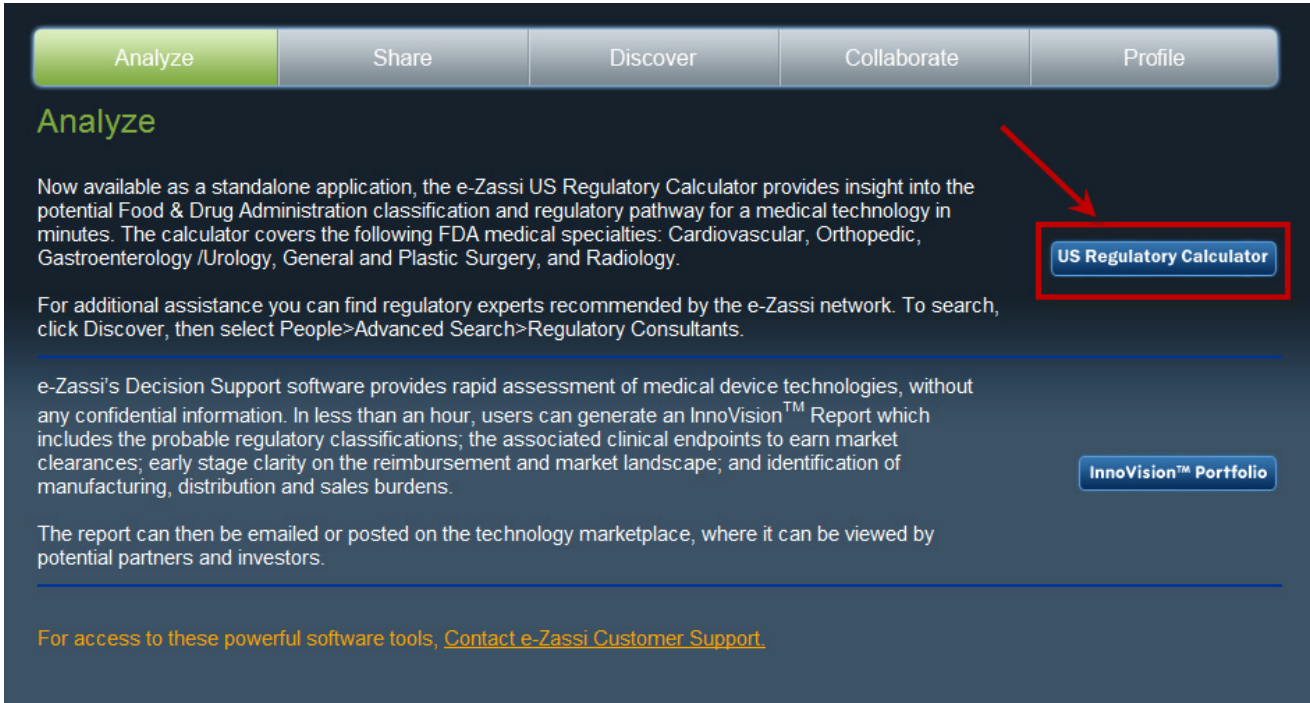
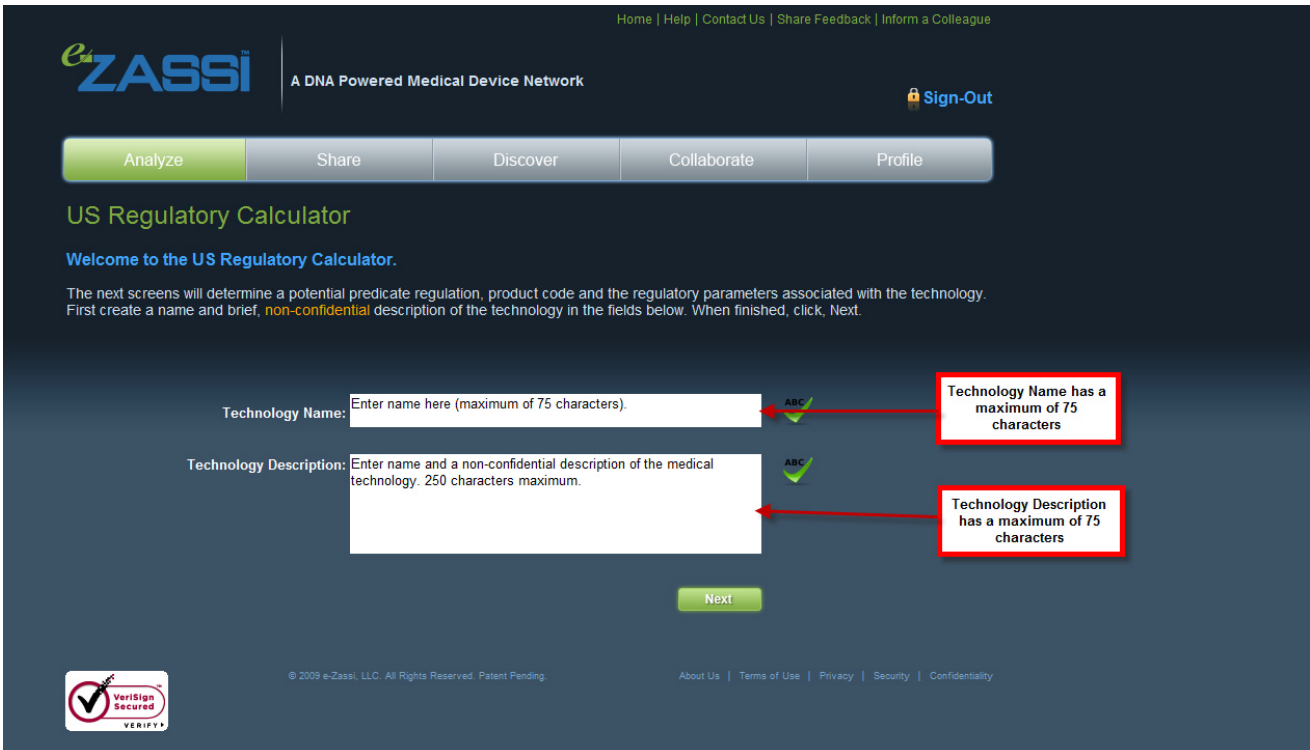
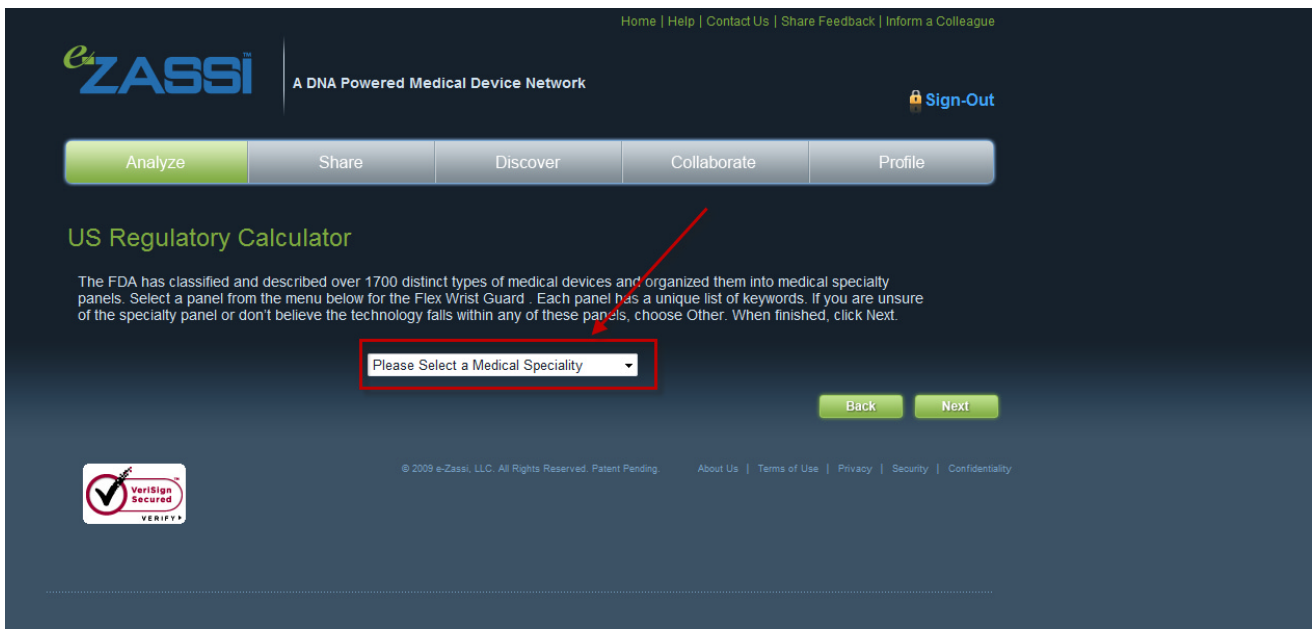


Figure 22b



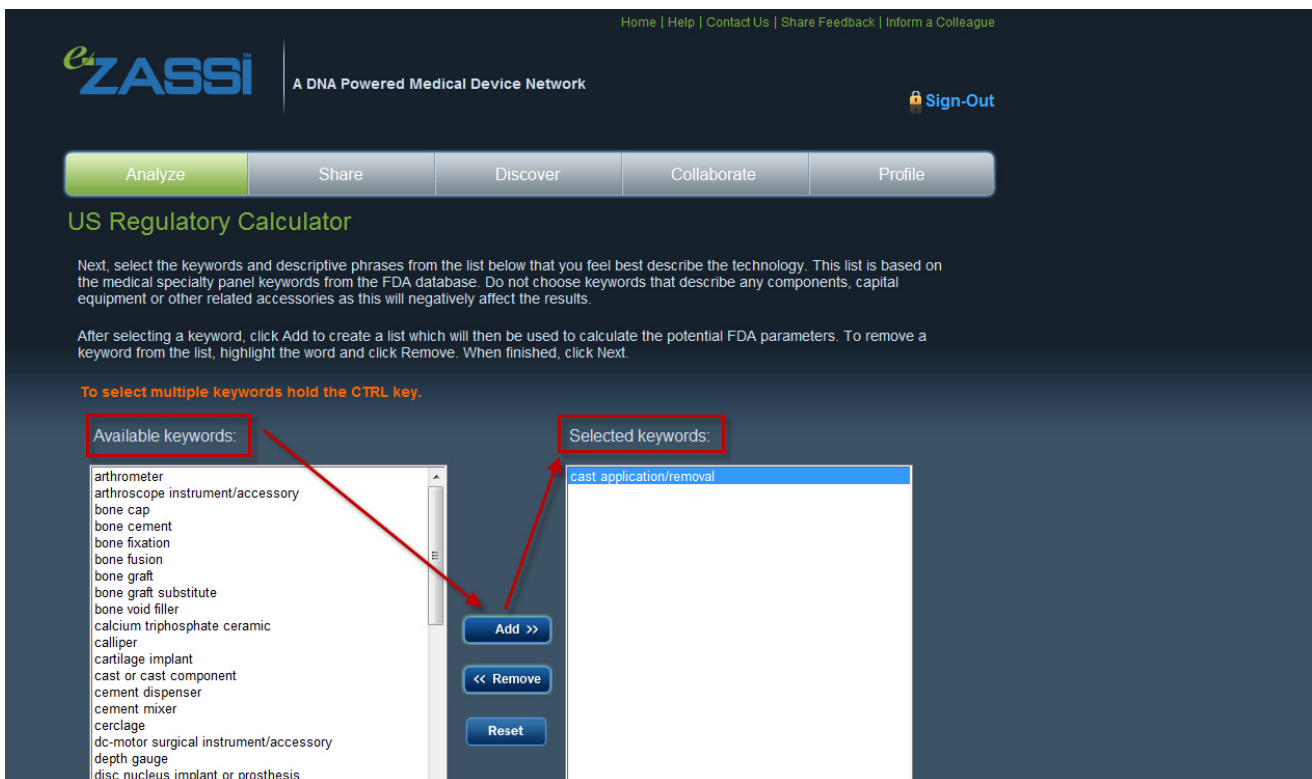
- From the Specialty Panel Page, select a medical device specialty from the dropdown (see Figure 23). Each panel has a unique list of keywords. Select Next to proceed.

Figure 23



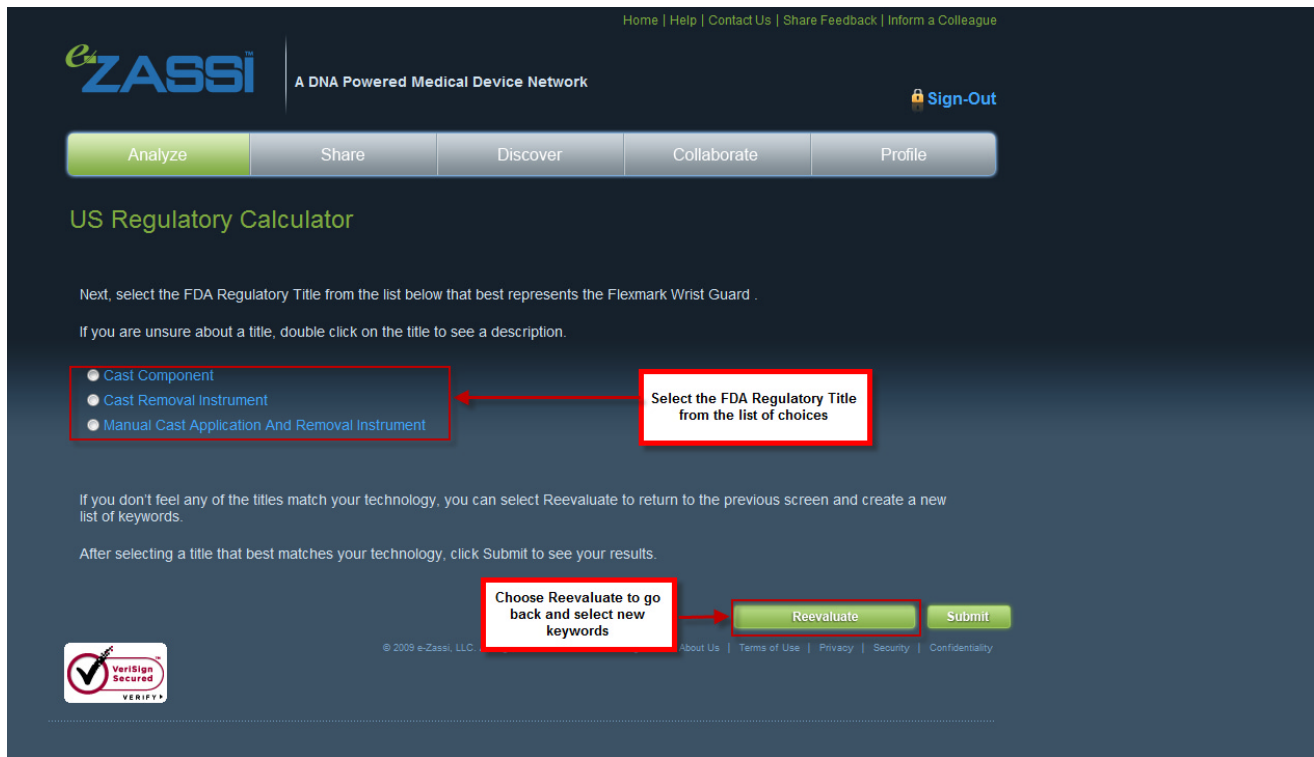
- From the Keyword Page, select the keywords and descriptive phrases that you feel best describe the technology. After selecting a keyword, click Add to create a list which will then be used to calculate the potential FDA parameters. To remove a keyword from the list, highlight the word and click Remove. When finished, click Next. (See Figure 24.)

Figure 24



- From the Regulatory Title Page, select the title from the list that best represents the technology. If none of the titles appear to match the technology, select Reevaluate to go back and select new keywords from the list. After selecting a title that best matches your technology, click Submit to see the results. (See Figure 25.)

Figure 25



- Based on the information provided, the e-Zasssi.com US Regulatory Calculator will display the following output: potential predicate, regulation number, product code and classification(s) and regulatory pathways associated with the technology.

You can create a PDF file of the e-Zasssi.com US Regulatory results by clicking on the PDF icon located in the upper right section of the screen. (See Figure 26.)

Figure 26

