Device Pass-through Web Application Crosswalk

| A | Web Application Section | Web Application Content | Screenshot | Burden | Modification |
|---------|--|--|-----------------------------|---|--|
| 15 F | -DA Info | Additional FDA Information from the already required FDA clearance documentation: Note: Utilizing slide format but will tweak questions to read: List the indication for which the Device Pass through is being submitted. If the device received a breakthrough indication from the FDA then list the indication for which the designation was received. (optional) | <form></form> | We do not anticipate any additional burden. The answers to these questions are in the FDA clearance documentation the applicant is required to attach to their application under the current process. | New |
| C | Substantial Clinical mprovements | Substantial Clinical Improvement Criterion Please Note: Utilizing slide format from NTAP application with modifications to the first paragraph to make it relevant for OPPS Device P-T purposes. CMS determines that a device to be included in the category will substantially improve the diagnosis or treatment of an illness or injury or improve the | <page-header></page-header> | None | Question added that was in the original paper application that was inadvertent ly not included in the MEARIS system when originally |

| Web | | | | |
|-------------|----------------------------|------------|--------|--------------|
| Application | Web Application Content | Screenshot | Burden | Modification |
| Section | | | | |
| | functioning of a | | | implement |
| | malformed body part | | | ed. |
| | compared to at least one | | | |
| | other currently available | | | |
| | and appropriate | | | |
| | treatment or diagnostic | | | |
| | test (ie. considered a | | | |
| | standard of care, | | | |
| | currently in use and | | | |
| | utilized by the Medicare | | | |
| | population). Whether a | | | |
| | candidate device | | | |
| | provides substantial | | | |
| | clinical improvement is | | | |
| | evaluated by one or | | | |
| | more of the following: a. | | | |
| | The device offers a | | | |
| | treatment option for a | | | |
| | patient population | | | |
| | unresponsive to, or | | | |
| | ineligible for, currently | | | |
| | available treatments. | | | |
| | Refer to the interim final | | | |
| | rule with comment | | | |
| | period in the November | | | |
| | 2, 2001 Federal Register | | | |
| | and the final rule with | | | |
| | comment period in the | | | |
| | November 1, 2002 | | | |
| | Federal Register (67 FR | | | |
| | 66781) and the | | | |
| | modifications to certain | | | |
| | criteria in the November | | | |
| | 10, 2005 (70 FR 68628) | | | |
| | final rule with comment | | | |
| | period for a full | | | |
| | discussion of the criteria | | | |
| | for establishing | | | |
| | additional pass-through | | | |

| | Web Application Section | Web Application Content | Screenshot | Burden | Modification |
|----|-------------------------------|---------------------------|--|--------|--------------|
| | | categories for medical | | | |
| | | devices. | | | |
| | | • Does the new medical | | | |
| | | service or technology | | | |
| | | offer a treatment option | | | |
| | | for a patient population | | | |
| | | unresponsive to, or | | | |
| | | ineligible for, currently | | | |
| | | available treatments? | | | |
| | | • Yes / No | | | |
| | | • Please explain why the | | | |
| | | technology does or does | | | |
| | | not meet this criterion | | | |
| | | using supporting data. | | | |
| | | • Text Box: Explanation | | | |
| | | 0/3000 | | | |
| 28 | | | | None | Question |
| | | Current treatments for | | | added that |
| | | the disease or condition | | | was in the |
| | Newness Criterion | that this technology | MEAR'S" A Hore Evitades B Applications () | | original |
| | | treats or diagnoses | wazad knowcem Sowell (Than Asne)(136x Tad baley Add an Pejerinza (1364))(Debal Tadar na Jacobery Debat Kini Tadholge An Tak Man Havesas (Debaj) Debig Olin Diaryi Vitanca Kasas Mataria Debat representent Sowely | | paper |
| | | • Are there any other | Current treatments for the disease or condition that this technology | | application |
| | | treatments for the | treats or diagnoses | | that was |
| | | disease or condition that | Are there only other treatments for the disease or condition that this technology treats or diagnoses? Yes Yes No | | inadvertent |
| | | this technology treats or | Briefly describe current treatments for the disease or condition. | | |
| | | diagnoses? | | | ly not |
| | | o Yes / No | 0.3000 | | included in |
| | | Briefly describe current | | | the MEARIS |
| | | treatments for the | Tack Text | | system |
| | | disease or conditions | | | when |
| | | o Text Box: Provide | | | originally |
| | | response 0/3000 | | | implement |
| | | | | | ed. |