Request Form for Investigational Device Exemptions (IDE) or Carotid Stent Clinical Studies (PMA)

The following form may be used when submitting the request to National Government Services.

Contact person for this request:

Name: _____

Address :_____

_____

_____

Phone number: _____

Email address: _____

Addressee (if different from contact person)

Name: _____

Request on behalf of (may be both categories):

☐ Facility(ies) (Medicare Part A)

☐ Individual practitioner(s) (Medicare Part B)

IDE number: _____

Study Name: _____

Trade name (device): _____

Common name of the device: _____

_____

Please submit the following site-specific information:

Facility(ies) where service will be provided:

Facility Name	Address	NPI (not UPIN)

Participating Practitioner (s):

	Name	MD/ DO	NPI (not UPIN)
PI			
Sub			
Sub			
Sub			
Sub			
Sub			
Sub			
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Sub			

Number of enrollees anticipated at the facility: _____

Anticipated bill type: (inpatient, outpatient, or both): _____

The following site specific documents are needed to process this request. They may be submitted in hard copy or electronic format.

1. A signed copy of the IRB approval letter.
2. A copy of the informed consent approved by the IRB.
3. A fully executed copy of the investigative agreement.
4. A list of any devices, supplies, drugs, or services for which the facility or physician will be reimbursed by the manufacturer.

The following documents specific to the study, trial, and/or registry are needed to process this request.

They may be submitted by either the sponsor or the provider.

1. A non-redacted copy of the FDA-approval letter provided to the sponsor or manufacturer of the device. The approved IDE code number and category designation must be on the letter.
2. A description of any action(s) taken to conform to any applicable IDE special controls.
3. A full copy of the applicable protocol.
4. A narrative description of the device sufficient to make a payment determination. (If this is part of the protocol, identify the page number(s).)

5. A statement indicating how the device is similar to and/or different from other comparable products. (If this is part of the protocol, identify the page number(s).)
6. At least two (2) supporting scientific articles (full texts) for the investigational device and its intended indication published in peer reviewed literature. (Not required for PMA on carotid stents.)

Providers requesting a continuation of coverage or an expansion of coverage for which National Government Services has already issued a letter of authorization should submit the following documents:

1. A copy of the original letter(s) from National Government Services approving the study.
2. A copy of the current IRB approval letter.
3. A copy of any documents that have changed since the original approval was issued (eg: consent form, protocol, investigative agreement, FDA letter).
4. If the request is for an expansion of the anticipated number of patients, what is the new total anticipated?
5. If the request is for the addition of sub-investigators or a change in the chief investigator, submit a list of the new physician investigator team. Indicate appropriate professional designation (eg: M.D. or D.O) and include the NPI numbers.