

WORK ORDER #: _____ **ISSUED TO:** Class Three, LLC
PURCHASE ORDER#: (optional) **PRODUCT:** _____
DATE ISSUED: _____ **SCOPE:** US Regulatory Path

This Work Order is being issued under and pursuant to the Master Services Agreement executed between [Client] and Class Three. In cases of a conflict between this Work Order and the Master Services Agreement, the Master Services Agreement shall take precedence.

1.0 Background

[Client] wishes to market a new medical device in the United States. The regulatory path for the device will depend on its technological characteristics, intended use, and the level of clinical risk associated with its use.

2.0 Scope of Work

[Client] would like Class Three's assistance in identifying the most likely US regulatory path for its medical device, based on its technological characteristics and intended use, and the associated regulatory requirements for this path.

3.0 Deliverables

- 3.1 [Client] will provide Class Three with a detailed description of the product, including materials, and a statement of the intended use for which [Client] plans to market the product in the US.
- 3.2 Upon execution of a Master Services Agreement and this Work Order and receipt of the specified retainer and product information from [Client], Class Three will research the regulatory paths that may be open to the product.
- 3.3 Class Three will provide [Client] with a written assessment of the likelihood that the product can be legally marketed in the US via each path, a list of the documents and other information that would be required in an FDA submission for each path, timelines and user fees associated with each path.
- 3.4 Class Three will also provide [Client] with copies of any applicable regulations, guidelines, and standards that Class Three identified in the process of its research.

4.0 Billing and Payment

- 4.1 [Client] will pay Class Three a retainer in the amount of \$_____. Class Three will invoice against the retainer for its services under this Work Order and will return any unused retainer to [Client] with its final invoice under this Work Order.
- 4.1 Class Three will invoice [Client] twice a month for regulatory consulting services performed under this work order, at an hourly rate of \$_____. A brief progress report will be included with each invoice.
- 4.2 Class Three will invoice a maximum of _____ hours under this Work Order without prior approval from [Client]. Approval to invoice for additional hours may be provided via email from [email address].

4.3 Invoices will be submitted via email to *[email address]*.

5.0 Effective Date

5.1 This Work Order will become effective once it has been signed by both **[Client]** and Class Three.

5.2 This Work Order will become null and void, and incapable of acceptance, if not signed and returned within 30 days of receipt, or if the specified retainer is not paid within 30 days of the Effective Date.

IN WITNESS WHEREOF, the Parties identified below have duly executed this Work Order as of the date set forth above as the Effective Date.

[Client Name]
[Client Address]
[Client Address]
[Client Phone]

CLASS THREE, LLC
1227 Seaton Road, #34
Durham, NC 27713
919-544-3366

Signature: _____
Name: _____
Title: _____
Date: _____

Signature: _____
Name: Julie Omohundro
Title: Owner and Principal Consultant
Date: _____