Abōva Consulting can assist you in obtaining U.S. Food and Drug Administration clearance or approval for your products.

Regulatory Plan

Preparing a detailed Regulatory Plan:

Each Regulatory Plan gathers information to road map U.S. Food and Drug Administration requirements and assist your company with commercialization of your device in the U.S.

Regulatory Submissions

Preparing Regulatory Submissions:

Each Regulatory Submission will be prepared within the applicable U.S. Food and Drug Administration regulatory framework.

Would you like help navigating the often-complex world of the U.S. Food and Drug Administration to introduce your unique products to the vibrant U.S. market?

Please email:

Consulting@abova-inc.com

Abōva Consulting

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Helping you navigate U.S. Food and Drug Administration to introduce your unique products to the vibrant U.S. market

Abōva Consulting offers:

Over 25 years of in-house expertise with the U.S. Food and Drug Administration.

Expert insight and guidance to efficiently introduce your product into the U.S. market.

Specialization in working with both established and startup companies with innovative medical and/or oral health device technologies or products which need assistance to gain entry into commercial sales in the U.S. market.

Tailored regulatory consulting services for specific client needs.

Regulatory Plan

If your company desires to enter the U.S. market, Abōva Consulting can guide your company by explaining in detail elements required to commercialize your device in the U.S., including:

- Device Classification, Product Code and Device Description
- Potential Predicates and Competitors
- Type of Submission
- Submission Timeliness and Cost
- Labeling Requirements
- Information Required in the Submission
- Import Requirements
- Establishment Registration
- Quality System and Manufacturing Expectations
- Distribution Requirements
- List of Applicable Standards

Regulatory Submissions

Abōva Consulting's preparation of Regulatory Submissions may include working with you to prepare:

- Pre-submission meetings with the U.S. Food and Drug Administration
- Pre-market notification (510(k))
- Pre-market approval application (PMA)
- Investigational device exemption (IDE)