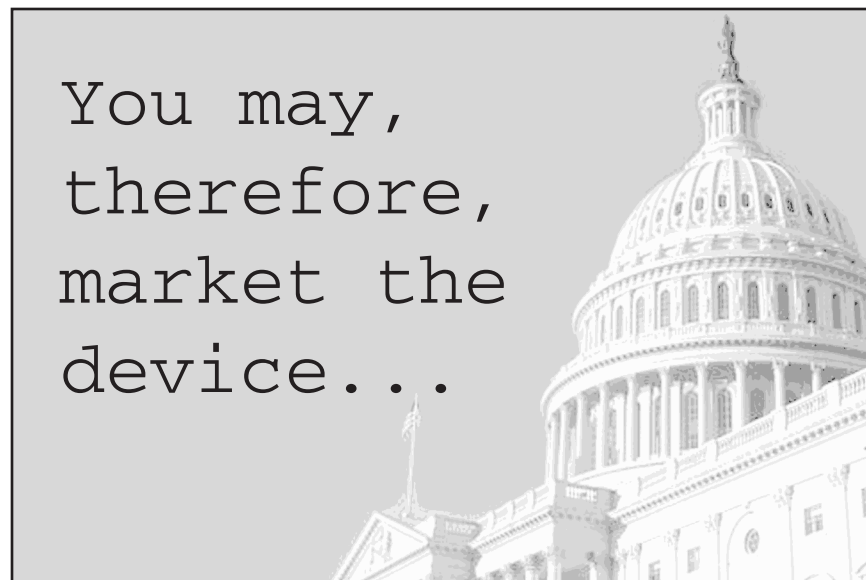


Realize your product's full market potential with broad FDA approvals.

Support and win the labeling claims you need.

- > **Implement the right registration strategy** by optimizing marketing, development, and approval trade-offs.
- > **Focus development activities** on achieving critical-path, approvable endpoints.
- > **Mitigate development risk** with proactively-negotiated approval pathways.
- > **Step up to early success** by linking near-term approval opportunities with post-market label expansions.
- > **Anticipate reimbursement** by early integration of cost-utility claims.



You may,
therefore,
market the
device...

Turnkey
510(k) & PMA
Approvals

Confidently Move Through Your Trials and Approvals

Our Approvals Practice delivers regulatory expertise, development strategy, and an outstanding track record.

- > Turnkey, integrated clinical development and approval engagements are our practice specialty.
- > Our practice focus: 510(k) and PMA approvals.
- > Responsive, experienced, and certified regulatory affairs, quality, and clinical development professionals.

About clinivation

Clinivation's business is productivity- taking the time and labor out of making better medical products.

Since 1999, our productivity software and solutions have delivered superior value to market leaders in medical devices, pharmaceuticals, and diagnostics.

For more information on our solutions and services, contact:

Business Development

508.655.6560 x222

solutions@clinivation.com

clinivation, Inc.

313 Speen Street

Natick, MA

01760-1538 USA

www.clinivation.com

Main 508.655.6560

Fax 508.655.6561

