Prosthetic Heart Valves - Pipeline Review, 2015

Reference Code: **GDME0006EPD**

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2 Introduction

2.1 Prosthetic Heart Valves Overview

Prosthetic heart valves have a passive mode of functioning; opening and closing of valves are responses to pressure and flow changes within the heart. Prosthetic heart valve includes both mechanical and tissue or biological heart valves.

- **Mechanical Heart Valves**

  Mechanical heart valves are generally made of non–physiological materials with a mobile occluder, which is made of rigid materials.

  Mechanical Aortic Valve Replacements

  Replacement of the aortic heart valve using a mechanical prosthesis. One unit refers to one mechanical aortic valve.

  Mechanical Mitral Valve Replacements

  Replacement of the mitral heart valve using a mechanical prosthesis. One unit refers to one mechanical mitral valve replacement.

- **Tissue Heart Valves**

  Tissue heart valve are a combination of tissue and synthetic biomaterials with the tissue itself being flexible. Bovine and porcine valves are included here.

  Tissue Aortic Valve Replacements

  Replacement of the aortic heart valve using a biological prosthesis. One unit refers to one tissue aortic valve.

  Tissue Mitral Valve Replacements

  Replacement of the mitral heart valve using a biological prosthesis. One unit refers to one tissue mitral valve.

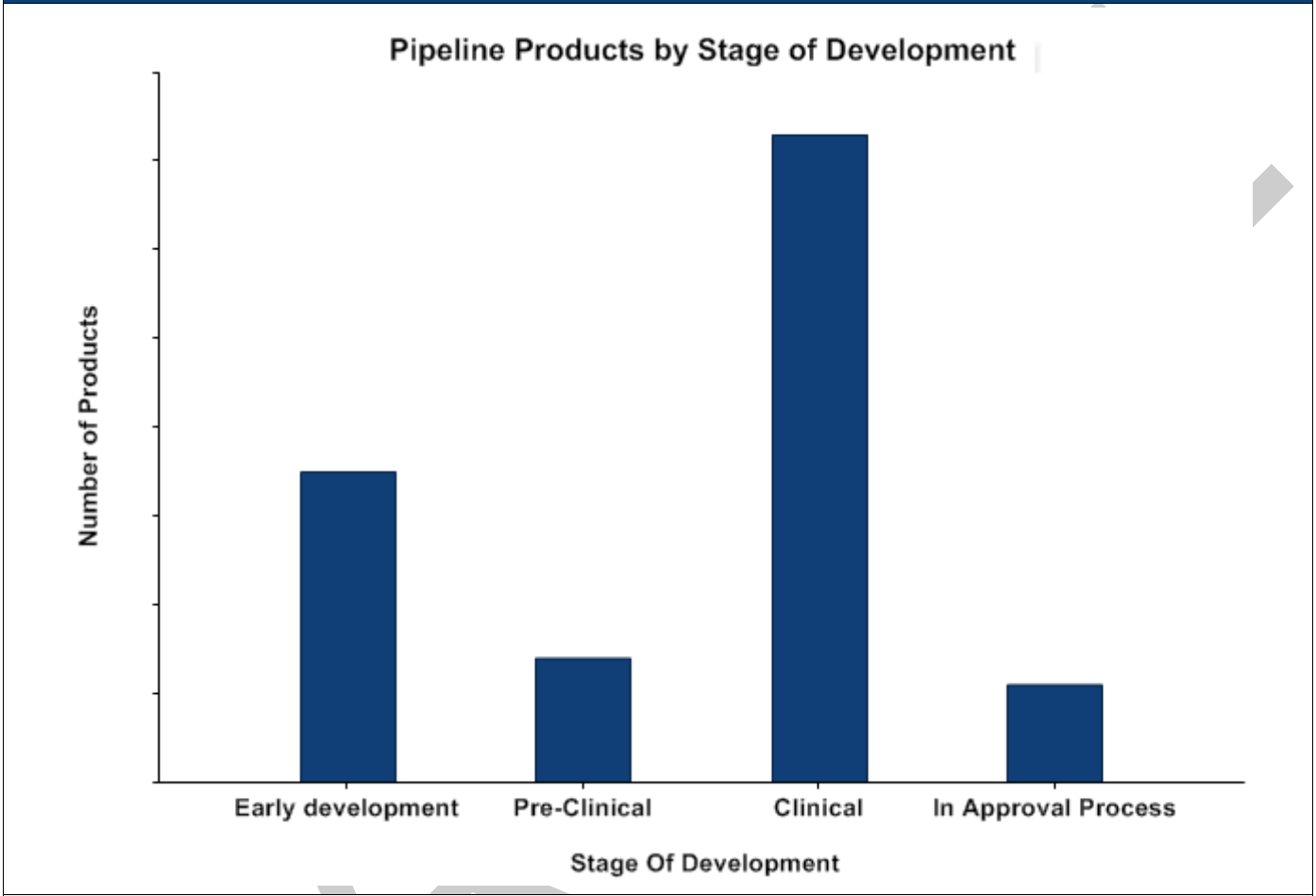
- **Transcatheter Heart Valves**

  The transcatheter heart valve is a tissue valve replacement that can be compressed down to the diameter of a pencil. It can be placed inside a beating heart using a catheter threaded through the patient's circulatory system or through a small incision between the ribs. Once inside the heart, the valve can then be opened into its natural position by the inflation of a balloon and deployed within the patient's diseased aortic valve. Only aortic valves replacements are tracked here. One unit refers to one transcatheter heart valve.

3 Products under Development

3.1 Prosthetic Heart Valves - Pipeline Products by Stage of Development

Figure 1: Prosthetic Heart Valves - Pipeline Products by Stage of Development



Source: Primary and Secondary Research, GlobalData

As of April, 2015

Table 1: Prosthetic Heart Valves - Pipeline Products by Stage of Development

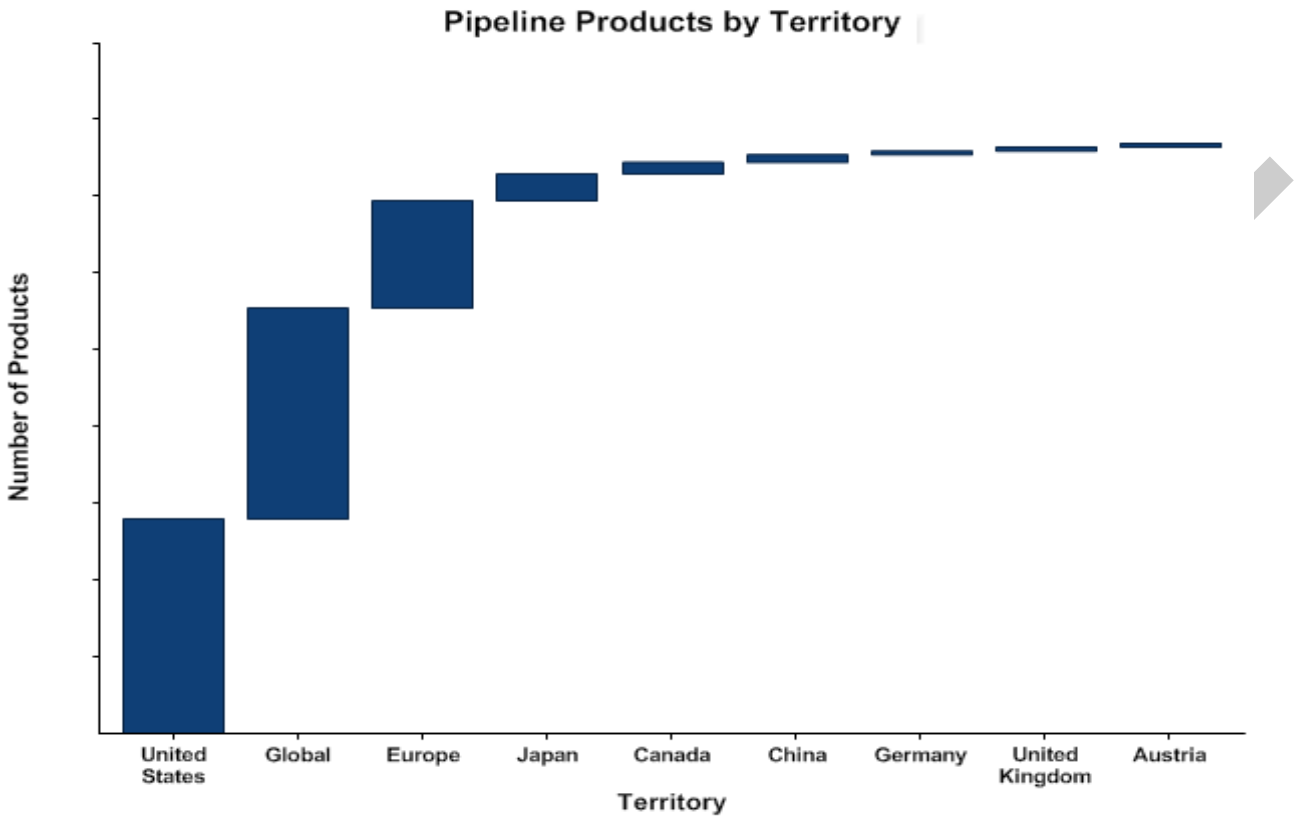
Stage Of Development	Number of Products
Early development	
Pre-Clinical	
Clinical	
In Approval Process	

Source: Primary / Secondary Research, GlobalData

As of April, 2015

3.3 Prosthetic Heart Valves - Pipeline Products by Territory

Figure 3: Prosthetic Heart Valves - Pipeline Products by Territory



Source: Primary and Secondary Research, GlobalData

As of April, 2015

Table 3: Prosthetic Heart Valves - Pipeline Products by Territory

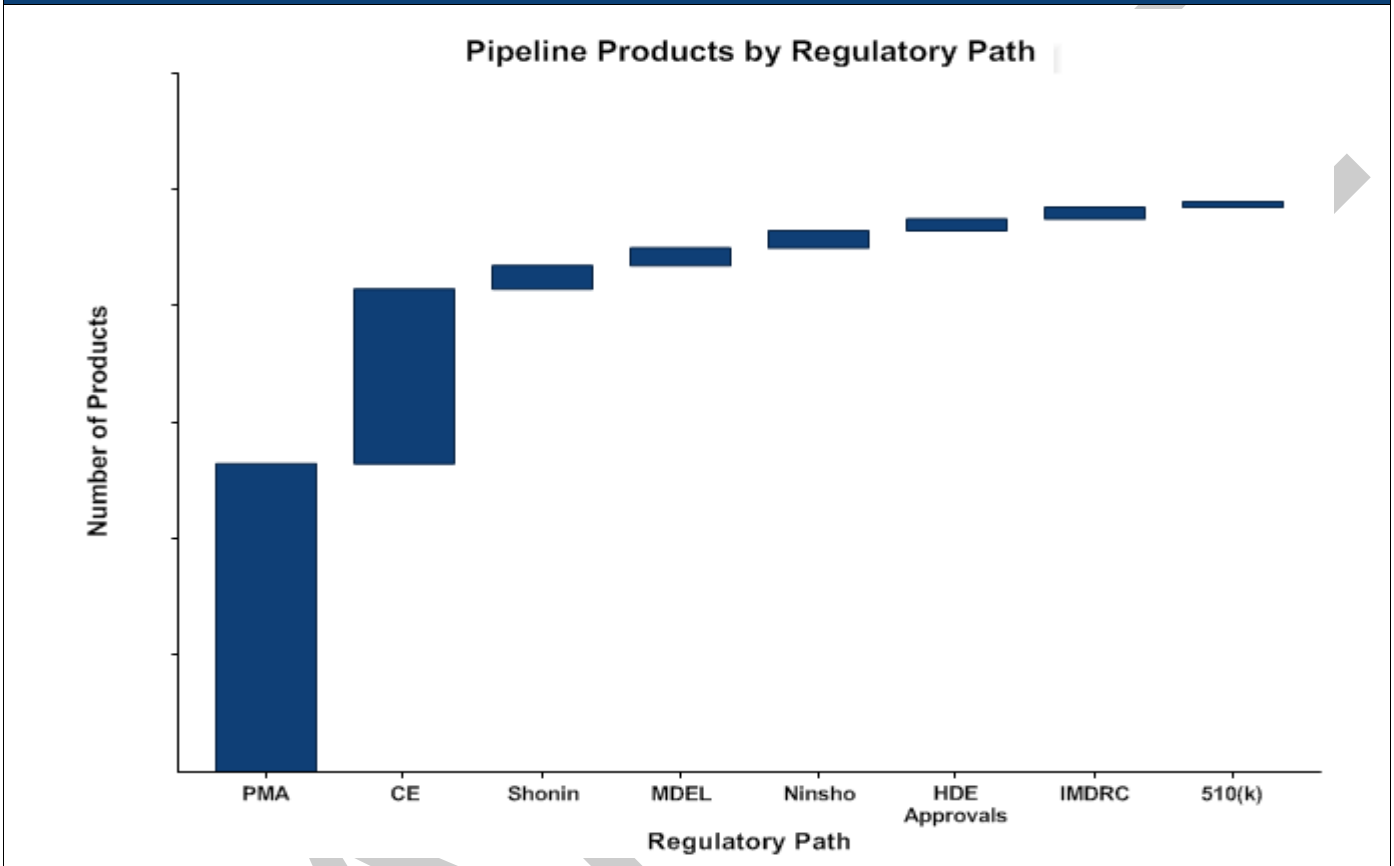
Territory	Number of Products
United States	
Global	
Europe	
Japan	
Canada	
China	
Germany	
United Kingdom	
Austria	

Source: Primary / Secondary Research, GlobalData

As of April, 2015

3.4 Prosthetic Heart Valves - Pipeline Products by Regulatory Path

Figure 4: Prosthetic Heart Valves - Pipeline Products by Regulatory Path



Source: Primary and Secondary Research, GlobalData

As of April, 2015

Table 4: Prosthetic Heart Valves - Pipeline Products by Regulatory Path

Regulatory Path	Number of Products
PMA	
CE	
Shonin	
MDEL	
Ninsho	
HDE Approvals	
IMDRC	
510(k)	

Source: Primary / Secondary Research, GlobalData

As of April, 2015

7 Appendix

The data and analysis within this report is driven by GlobalData.
GlobalData gives you key information to drive sales, investment and deal making activity in your business.
Our coverage includes 200,000 + reports on 185,000+ companies (including 150,000+ private) across 200+ countries and 29 industries. The key industries include Alternative Energy, Oil & Gas, Clean Technology, Technology and Telecommunication, Pharmaceutical and Healthcare, Power, Financial Services, Chemical and Metal & Mining.

7.1 Methodology

GlobalData company reports are based on a core set of research techniques which ensure the best possible level of quality and accuracy of data. The key sources used include:

- Company Websites
- Company Annual Reports
- SEC Filings
- Press Releases
- Proprietary Databases

Taxonomy:

GlobalData has developed an industry-leading four tier (market, category, segment, subsegment) medical devices taxonomy. The taxonomy is both comprehensive and constantly updated ensuring data quality. The report published is a category based report where the product taxonomy vary from category level to sub-segment level.

Origination:

GlobalData's pipeline products and clinical trials data is built using information and data from a number of important sources based on both internal and external sources to develop a comprehensive and robust view of the medical devices market.

Secondary Research:

Extensive secondary research is done to gather data specific to the pipeline products and clinical trials. We track medical devices that are in development related to nearly 18 markets (ie, cardiovascular devices, dental devices etc) that we cover.
GlobalData conducts extensive research to gather data specific to pipeline products (product status, current stage of development, product description, technology and estimation timelines of medical devices) and clinical trials. Hundreds of medical specific live news sources are monitored on a daily basis.

Primary Research:

Primary research is conducted to validate the product status, stage of development and estimated timelines.
GlobalData's pool of primary research candidates for the pipeline products enquiries includes marketing / product managers, R&D director, sales director and key person involving with regulatory process.

Updates:

All pipeline products are updated at least once in a quarter. Products are updated through secondary research sources such as live news, press releases, company websites, presentations, sec filings, transcripts etc.

GlobalData uses an in house template to estimate product approval date and product launch date in case if data is not obtained either through secondary or primary research. The template uses various parameters (pipeline territory (region), device class, stage of development, product source date) to analyze and estimate the product approval/launch date.

A wide range of factors are considered while estimating timelines for the medical devices.

Notes

• Financial information for the company is taken from the most recently published annual reports or SEC filings

• The number of products mentioned in various graphs can be inconsistent due to plotting of different fields

• Pipeline Products by Stage of Development Graph - Displays exact count of pipeline products

• Pipeline Products by Segment Graph - Products tagged directly to sector is not included but its sub-level tagging is shown

• Pipeline Products by Territory Graph - Displays count of all multiple territories tagged to pipeline products

• Pipeline Products by Regulatory Path Graph - Displays only count of territories for which Regulatory Path is defined

• Pipeline Products by Estimated Approval Date Graph - Displays count of all estimated approval dates tagged to multiple territories

• Only the below mentioned status of Clinical trials are included in the report specific to the pipeline products:

Ongoing, Recruiting

Ongoing, not Recruiting

Ongoing, Recruiting by invitation

Ongoing, not yet recruiting

• Recent Development section covers news posted during last six months

• GlobalData considers regulatory approved (Approved and Issued) products as pipeline in case products are yet to launch in the market.

Table 395: Glossary

Field Name	Definition
Product Name	Indicates product name
Developed By	Provides information of the company which develops the product
Product Description	Provides information on product (What is the condition, where it will be used, benefits, technical specifications etc)
Indication	Provides information on the therapeutic or diagnostic conditions where the product is used
Application	Indicates the procedure or intervention for which the selected product is used
Device Class	Provides product class information based on their design complexity, characteristics and risk factors i.e. Class I, II and III
Highest Stage of Development/Development stage	Provides information on the developmental status e.g. early development, pre-clinicals, clinical, in approval process
Territory	A geographic region where the product is currently in pipeline or will be commercially launched
Estimated Approval Date	Provides information on expected product approval date
Market Category/Equipment Type	Indicates the classification of a medical device based on therapy area and application
Regulatory Path	Regulatory process through which the product gets marketing

	approval by respective regulatory agency
Technology	Indicates the core technology used in product
Function	Provides information about the mechanism of action of the device
Early Development	Defined when a product is in prototype or design stage of development
Pre Clinical	Defined when a product is tested in animals
Clinical	Defined when a product is tested in humans for the safety and efficacy of the device
In Approval Process	Defined when a product is filed for approval with regulatory body for approval of the product
Issued	Defined when a product receives regulatory approval from European Union
Approved	Defined when a product receives regulatory approval from a country other than Europe
Planned (Ongoing, not yet Recruiting)	The participants are not yet to be recruited or enrolled for the study
Ongoing, Recruiting	The participants are currently being recruited or enrolled for the study
Ongoing, not Recruiting	The study is still ongoing. The patients are being treated or examined or study results are being analyzed for its endpoints. But enrollment for the study stands completed
Ongoing, Recruiting by invitation	The participants are being (or will be) selected from a predetermined population (as decided in advance by the researchers)
Global (Pipeline territory)	If source does not indicate any specific country as pipeline region, then Global is added as the pipeline territory
Source: Primary / Secondary Research, GlobalData	
As of April, 2015	

7.2 About GlobalData

GlobalData is one of the world's leading providers of company operational data and strategic analysis, providing detailed information on tens of thousands of companies globally. Our highly qualified team of Analysts, Researchers, and Solution Consultants use proprietary data sources and various tools and techniques to gather, analyze and represent the latest and the most reliable information essential for businesses to sustain a competitive edge. Data is continuously updated and revised by large teams of research experts, so that it always reflects the latest events and information. With a large dedicated research and analysis capability, GlobalData employs rigorous primary and secondary research techniques in developing unique data sets and research material for this series and its other reports. GlobalData offers comprehensive geographic coverage across world's most important sectors, focusing particularly on energy and healthcare.

7.4 Disclaimer