

Medical Devices: Burgeoning industry has plenty of opportunities in wearables, old age care and neurology

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Abstracts

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SUMMARY

The medical device market is extremely broad in its scope and covers devices as innocuous and simple as bandages and condoms, right through to highly sensitive, technologically advanced and critical devices such as pacemakers and implants. The medical device market has good opportunities ahead of it and excellent growth is being seen in neurology, diabetes and wearables as innovative new devices are providing solutions to problems that were previously considered unsolvable. However, the market has its incoming challenges too.

Many regions are seeing healthcare budgets fall or remain static and regulatory bodies are now highly involved in the efficacy process, taking choice away from doctors in many instances. These factors are putting pressure on medical device products, in many cases driving down the price, which is causing difficulty at the premium end of the market as new innovative products have much less time to earn profit before they are swamped with alternatives. Furthermore, some significant changes need to take place in terms of regulation, both to make products safer and to speed up approvals for innovative tech products, both of which will be very hard to achieve.

KEY HIGHLIGHTS

The medical device market is changing as pressure on healthcare budgets,



regulation changes and high levels of competition are forcing players to think about new ways to present their products. Increasing numbers of nonclinical actors are involved in the procurement process and this means that in some countries, premium and highly specialized product are getting squeezed, while highly innovative breakthroughs are being copied and reworked quickly.

All of these factors are forcing down prices in the market; while this is good for patients and buyers, medical device players are changing their business models to adapt. Increasingly they are using business to consumer strategies and bringing tech partners on board to help them. But they could go further still; there is a possibility that some medical device firms might create "mega plays" in the supply chain, absorbing distribution channels and even players themselves to create an "all under one roof" type of medical business.

Wearable devices are the new hot topic within the medical device market. Much has been said and written about how smart devices, some intended for other purposes, can be adapted and developed to produce powerful new tools to measure all manner of health issues. The beauty of many of these solutions is that they can be consumer focused and sold retail, direct to the consumer in some cases, allowing manufacturers to completely bypass the traditional medical prescription structure. However, there are issues; many of the claims that some of these devices make are not regulatory body approved and, in some cases, can make consumers overly paranoid and confused by their results. Nevertheless, wearable medical devices provide a significant opportunity for manufacturers to spread their tech to a broad audience and provide useful analytical tools.

Currently, the aims of brain computer interfaces are two-fold. The first is to use our greater knowledge of the brain to create devices that can assist and repair brains that have been damaged in some way. The second is to augment the ability of a brain to do much more than it already can. Scientists have made great breakthroughs in neuroscience using implanted neurons in the brain to help repair vision, hearing and paralysis. The next step is to develop less invasive methods of achieving the same goals with an eye by producing implants that can enhance a human's ability to input and output information from the brain, to achieve things such as brain-to-brain communication and enhancing the brain's ability by connecting it to computers. The proponents of this technology see it as a necessary development in order for humans to keep pace with technologies such as AI. Neurology is actually the fastest-growing



specialty area of medical devices, estimated to be expanding at a rate of 13.7% per year.

SCOPE

Examine how the medical device industry is developing and what new business techniques players might use

See what the emerging technologies are and how they are spreading

Understand the impact of wearables in the medical device segment

See how technology is improving neurological treatment

See how regulation could be an issue in the industry and what might regulators do in future.

REASONS TO BUY

Is regulation in the US and EU unfit for purpose?

Who are the biggest medical device players and who is spending the most on R&D?

What are the most rapidly developing medical device sectors?

How is technology unlocking new treatment possibilities?



Contents

Executive Summary

Medical devices: Very diverse market and new business models are emerging Wearable Medical Devices: Segment is seeing significant technological innovation Neurological Implants: Segment is seeing significant new growth for medical devices Aging Demographics: A highly important segment for medical devices Medical Devices: new business models are emerging to suit the changing regulatory environment

Medical devices are extremely diverse and compete in different segments

Class I includes low risk devices such as bandages and stethoscopes

Class II includes moderate risk devices such as wheelchairs

Class III devices include the highest risk devices, such as pacemakers or implants

US and EU regulatory pathways are only similar on the surface

Concerning cases of defective and dangerous medical devices have surfaced, leading to questions over regulation

FDA device regulations have been inadequate for a number of years

Competitors starting to move in on Medtronic over next decade

Constricted healthcare budgets mean players have to plan carefully

Blockbuster treatment areas are now becoming quite crowded

The medical device industry is changing, and players need to adapt

New business to consumer models are popular at present

Future business models might involve a "mega play" across the value chain

Amazon might soon become a significant competitor in healthcare

Growth of the Chinese medical device market is significant but western players are less welcome

Wearable Medical Devices: Segment is seeing significant technological innovation Apple Watch and Apple Health App are strong market offerings acting as potential substitutes

Other companies can piggy-back on good wearable devices

Global levels of diabetes are expected to rise, providing a huge opportunity for medical device manufacturers

Guardian Connect from Medtronic is part of a new wave of wearable diabetes devices Insulin pumps offer an advanced level of diabetes treatment

Remote monitoring becoming the new industry goal

Kardia Band from AliveCor is another device using wearables, but with a subscription business model

Remote monitoring can lead to patient disengagement Simplicity could be a route to faster regulatory approval



Regulation for wearables has been obsolete for a number of years The FDA itself is aware of this problem and is taking steps to improve the process Neurological Implants: Segment is seeing significant new growth for medical devices Assisting brains that need repair is a key aim of neural implants and BCIs Cochlear implants are very common place, non-invasive and can restore senses Deep brain stimulation can alleviate the symptoms of Parkinson's disease Retinal implant technology is allowing the blind to see again through a bionic eye Treatment of spinal injuries to allow patients with paraplegia to move again Microfibers are becoming more advanced and this is opening up new possibilities The next step for BCIs is human enhancement

DARPA has been working on this field for a number of years for defense purposes Kernel is looking to find ways to improve human intelligence and cure disease Neuralink is planning to create an AI interface between the brain and computers Even successful programs have shown that side effects can be severe Aging Demographics: A highly important segment for medical devices New alert technology allows elderly people to stay at home, keeping many out of care systems

Internet of things is changing how care is delivered to an aging population New medical devices coming to the market include bespoke artificial limbs New generation of smart pacemakers could be susceptible to hacking Nascent technology can radically improve the mobility of an aging population, creating new business

Toyota's Mobility Challenge means better solutions to lower limb paralysis are coming Mobility presents growing business opportunities for innovation

Remotely taking doctors into homes: technology streamlines treatment of elderly patients

Communication technology designed for over 65 year olds is a growth industry Many of the latest devices are perfect for seniors, but not marketed as such Key Findings

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