

FDA considers

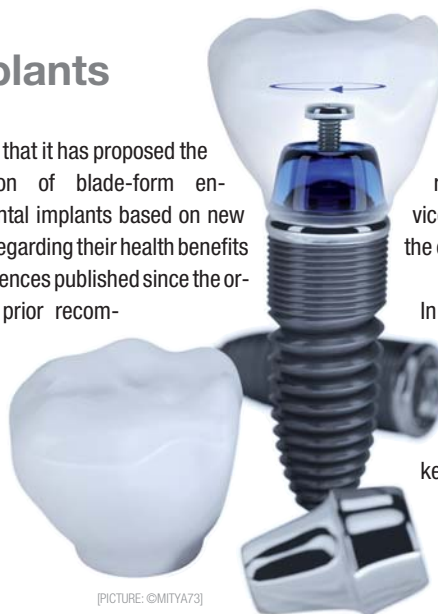
Reclassification of dental implants

The American Food and Drug Administration (FDA) has proposed a reclassification of blade-form endosseous dental implants commonly used in dental restoration from Class III to Class II devices, reducing the regulatory requirements for marketing these implants.

The FDA recognises three classes of medical devices based on the level of control necessary to assure safety and effectiveness. While Class II devices, i.e. medium-risk devices, are subject to general and special controls, Class III devices are highly regulated. Usually, Class III devices support or sustain human life, or are of substantial importance in preventing impairment of human health, but may present a potential, unreasonable risk of illness or injury.

In many cases, premarket approval is required to ensure the safety and effectiveness of these devices.

The FDA said that it has proposed the reclassification of blade-form endosseous dental implants based on new information regarding their health benefits and risk incidences published since the organisation's prior recom-



mendation. "FDA has been reviewing these devices for many years and their risks are well known. A review of the applicable clinical literature indicates that the device has a high success rate and that few relevant adverse events have been re-

ported in the case of these devices or related devices, suggesting that the device has a high long-term safety profile," the organisation stated.

In addition to complying with general controls, the implants would be subject to special controls, including special labelling requirements, mandatory performance standards and postmarket surveillance.

However, premarket approval would no longer be mandatory to effectively mitigate possible health risks, including infection and adverse tissue reactions.

Electronic or written submissions on the proposal can be submitted by April 15, the organisation stated.

EU health-care sector faces

Serious recruitment problems



The EU health-care sector is facing hard times. With an ageing work-force and insufficient new recruits to replace those who are retiring, the future does not look promising. Owing to demanding working conditions and relatively low pay in some health occupations, recruits are not attracted to the sector. A while ago, the EU member states invited the EC to propose an action plan to assist them in tackling the key challenges facing the health work-force in the medium to longer term. This commission staff working document describes the current status of the sector, among other matters.

The health-care sector comprises workers who primarily deliver health-care services, including health professionals (doctors, nurses, midwives, pharmacists and dentists), allied health professionals, public-health professionals, health management, and administrative and support staff. Some people also

work for the health-care sector indirectly, such as those employed in the health-care industries and support services, pharmaceuticals, medical device industries, health insurance, health research, e-health, occupational health, spa, etc. Most health-care workers are female. More than 13.1 million women were employed in the sector in 2010, making up more than three quarters of the health work-force in the entire EU. Health care is one of the largest sectors in the EU, with around 17.1 million jobs in 2010, which accounts for eight per cent of all jobs in the EU-27. The number of jobs in the sector increased by 21 per cent between 2000 and 2010, creating four million new jobs. According to the EC document, the health-care sector even continued to grow during the economic crisis, with the positive trend reflected in all age groups. Forecasts predict that it will remain a growing sector, even though employment growth will be more modest compared with 2000 to 2010.

Dental implants market

Will double by 2018

According to business report provider GBI Research, the dental implants market is set to almost double in value over the next six years. Owing to technological advancements and the aging population worldwide, the company expects a rapid increase in the use of dental implants in the near future. An analysis of the market for titanium and zirconium dental implants revealed that the global dental implants market is expected to grow at a compound rate of 10 per cent from \$3.4 billion in 2011 to \$6.6 billion in 2018, GBI Research's health care experts said. They found that the market is mainly driven by growing concerns about oral hygiene, increasing life expectancy and the availability of advanced solutions for dental implants based on digital dentistry, which increases procedure efficiency and reduces the incidence of adverse outcomes. Moreover, the investigators observed an increasing preference for dental implants as a treatment option over conventional devices such as crowns, bridges or dentures.