The Office of Science and Engineering Laboratories (OSEL) serves as the Center of Devices and Radiological Health (CDRH) research arm to support the assessment of the enormous breadth of devices that the Center regulates, from MRI scanners and neural stimulation devices to pacemakers, cancer treatments and other lifesaving products.

Ensuring readiness for emerging and innovative medical technologies

The pace of innovation and introduction of new technology in medical devices continues to accelerate. It is imperative for the FDA to anticipate trends to ensure that it can appropriately assess the safety and utility of new medical products when they are presented to the FDA. A great example is the introduction of 3D printing, which is now in common use in medical devices. By the time that the FDA started to receive applications involving 3D printing, we knew the most important questions that needed to be answered, resulting in faster clearances and confidence that the devices were effective and safe for use.

Developing appropriate evaluation strategies and testing standards

Standardized testing methods have enormous benefits for both industry and the FDA, and therefore patients. The use of methods that are both well characterized and broadly accepted is a vital part of providing industry with predictable and science-based processes for the introduction of new medical products. FDA can reduce the time to review applications, accelerating the process of timely access to life-saving medical products.

Creating accessible and understandable public health information

The research that OSEL conducts results in a high number of peer reviewed publications each year. The information is publicly available and used by industry, patient advocacy groups, academia and other stakeholders to promote public health initiatives.

Delivering timely and accurate decisions for products across their life cycle

For some advanced technologies and product areas, OSEL acts as a scientific consultant to our FDA colleagues in the approval and clearance of novel devices. This is an integral function of the review process which ensures that patients in US have timely access to the broadest possible portfolio of products to treat diseases and improve the nation’s health.

www.fda.gov