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Medtech approvals of the strange kind

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2015 is on track for the greatest number of novel medical device approvals in the US in a decade, with 47 FDA premarket approvals and humanitarian device exemptions (HDE) as of December 23. In addition, it might also have seen some of the weirdest.

The HDE route arguably attracts the quirkier devices, as it addresses rare diseases where there are few other options, leaving the FDA more likely to take a chance on a new approach. But perhaps quirkier still are those gaining *de novo* clearance – 17 products had gone down this route by December 23. This is likely due to the fact that to be granted *de novo* clearance a device only has to pose low to moderate risk with a "reasonable assurance" of safety and efficacy.

Obesity devices

Obesity was a rich hunting ground last year for companies with slightly wacky products, helped by the world's growing waistlines and paucity of effective weight loss interventions.

Enteromedics' Maestro was the first to get the go-ahead in January, via the PMA route (*US approval for Enteromedics' expensive weight loss shocker, January 15, 2015*). The implantable pacemaker-like device delivers electrical impulses to intermittently block the vagus nerve, which is said to control hunger and fullness.

Enteromedics' Maestro

If the approach sounds unlikely, it might well be – the approval came in spite of an endpoint miss in Maestro's pivotal US trial (*Trial miss gives EnteroMedics a jolt, but approval push continues, February 11, 2013*).

But perhaps the strangest obesity device, which is CE marked, but does not yet have FDA approval, is Aspire Bariatrics' AspireAssist – essentially a tube placed in the stomach that is connected to a port on the outside of the abdomen that allows patients to jettison part of a meal before it is digested.

Sensitive topics

Another interesting device to get approved, at the opposite end of the digestive spectrum, was Pelvalon's Eclipse system for the treatment of faecal incontinence in women. The device comprises a balloon that is inflated in the vagina – the resulting pressure on the rectal wall prevents involuntary bowel movements. The product received *de novo* clearance in February.

Pelvalon's Eclipse

Taking a different approach to incontinence was Torax Medical's, whose Fenix was approved via an HDE in December. The product consists of a band of magnetic beads that is placed around the anal sphincter to stop involuntary opening. According to the company, the magnetic bond is temporarily broken to allow the voluntary passage of stools.

Torax also got FDA approval for its next-generation MRI-compatible Linx oesophageal reflux management

system, which similarly employs magnetic beads, in June.

Like faecal incontinence, premature ejaculation is a sensitive topic, and an area where drugs have failed to make much of an impact – Johnson & Johnson's Priligy springs to mind. Enter Ergon Medical, which has developed Prolong, a vibrator to prevent premature ejaculation. This might sound counterintuitive, but it is designed to be used repeatedly in "training" to eventually reduce penile sensitivity. The device was cleared via the *de novo* route.

Also getting *de novo* clearance was INVO Bioscience's fertility treatment INVOcell, a capsule for the incubation of eggs and sperm in the woman's vagina, rather than in the lab as with IVF. INVO says its technology is cheaper than IVF and decreases the risk of multiple births, as well as providing a "more personal" approach.

Military might

Devices originally designed for military use also tend to be unusual. One example is RevMedX's XStat 30, a gunshot wound dressing that received 510(k) clearance in December (*Battlefield gunshot dressing cleared for US civilian use, December 09, 2015*). XStat 30 is an injector filled with dozens of small sponges, which expand inside the puncture wound to control bleeding.

Meanwhile, the quest for bionic limbs and organs has thrown up some weird and wonderful devices. Second Sight's Argus II "bionic eye" has been approved since 2013, but a new contender is Wicab's BrainPort V100, which was granted de novo clearance in June.

The system includes a video camera mounted on a pair of sunglasses linked to an array of electrodes that the user holds in their mouth. Pixels on the video feed are translated into electrical impulses that are felt on the tongue, to help blind people with orientation and mobility.

The field of neurology has also provided some interesting technology. Deep brain stimulation, once in the realm of science fiction, is now pretty mainstream, so something different is needed in order to raise eyebrows.

One new approach to treating major depressive disorder is transcranial magnetic stimulation – the stimulation is delivered outside the brain, making it less invasive than DBS. The latest TMS device to be approved in the US is MagVenture's MagVita, which received 510(k) clearance in August for drug-resistant depression.

The real question about TMS is whether it actually works, and many of the other devices above also face challenges in proving their worth. But in most of the diseases involved there are currently limited options – and it seems that in these cases, the FDA is not averse to taking a chance on something out of the ordinary.

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