Lambda Research Newsletter

February 2021

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Research Accelerated

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Clinical Research NEWS letter

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GLOBAL NEWS

1. Artificial intelligence improve and speed up drug discovery

Pharmaceutical company develops new cutting-edge technology for diseases such as cancer, rheumatoid arthritis and Alzheimer's using artificial intelligence. According to analytics firm GlobalData artificial intelligence improve and speed up drug discovery, potentially.

Since 2015 almost 100 partnerships have been struck between AI specialists and large pharma companies for drug discovery.

Artificial intelligence uses automated machine learning algorithm, it detects hidden patterns and perform task within a seconds that would usually takes months.

According to the US research firm Trinity Life Sciences approximately 90% of large pharmaceutical firms initiated AI projects last year. AstraZeneca and GSK, Britain's two biggest drugmakers, committed a five-year partnership with Cambridge University. The 15-strong team will develop AI and machine-learning technologies to improve clinical trials, personalized medicine and drug discovery.

Source: theguardian.com

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GLOBAL NEWS

2. Mass spectrometry for drug discovery and development

In pharmaceutical research mass spectrometry has numerous uses, it's applicable from initial discovery through to characterization and quality control. In pharma regulatory and drug development mass spectrometry established novel applications of the technique in drug discovery and development.

Mass spectrometry has been used in the pharmaceutical and biotechnology industries for over half a century.

MS application in drug discovery, research and subsequently in the development, characterization and quality control of pharmaceuticals, both for small molecule drugs and biologics.

MS has continued to expand its role in drug discovery and development and make inroads in new areas of pharmaceutical and biopharmaceutical R&D.

Source: europeanpharmaceuticalreview.com

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GLOBAL NEWS

3. Tailoring botulinum toxin proteases to target new proteins

HARVARD UNIVERSITY

The researchers from Harvard University and the Broad Institute have proved rapidly evolve the toxin in the laboratory to target a variety of different proteins and creating a suite of bespoke, super-selective proteins known as proteases with potential help in neuro regeneration, regulate growth hormones, calm rampant inflammation, or dampen the life-threatening immune response called cytokine storm.

A team of researchers have successfully reprogrammed proteases enzymes that cut proteins to either activate or deactivate them to cut entirely new protein targets with little or no similarity to the native targets of the starting proteases, and to avoid joined their original targets.

Botulinum toxin proteases can enter neurons in large numbers and giving them a wider reach that makes them all the more appealing as potential therapeutics.

Currently, the team's technology can evolve custom proteases with tailor-made instructions for which protein to cut, such capability could make editing the proteome feasible.

Source: technologynetworks.com

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GLOBAL NEWS

4. Novel drug candidates for the treatment of obesity and diabetes

The German researchers have conducted study and say that dual-agonists targeting the receptors for Glucagon-like peptide 1 (GLP-1) and GIP plays a crucial role in the regulation of body weight and novel drug candidates for the treatment of obesity and diabetes.

The researchers combined hormones in a single molecule that acts equally at the receptors of the insulin-stimulating hormones GLP-1 and GIP. The dual agonist lowers body weight and improves blood glucose levels.

These findings may use in the development of novel drug targets that improve the signaling and effect of the GIP receptor. This could help to further increase the metabolic benefits of treatment with GIP and GLP-1/GIP.

Source: drugtargetreview.com

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PHARMA INDIA

1. Covishield approved as an emergency use

AstraZeneca and US pharmaceutical major Novavax have ready to production of Covid-19 vaccines in partnership with the Serum Institute of India. Coronavirus vaccine developed by AstraZeneca and Oxford University, which is known as Covishield.

Covishield was approved emergency use listing by the WHO this month together with the Serum Institute of India.

They planned to supply over 300 million doses to 145 countries through Covax in the first half of 2021.The majority supply will go to low and middle-income countries.

Source: indiatoday.in

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PHARMA INDIA

2. Government of Telangana partners with Cytiva

A global life science leader Cytiva and the State of Telangana in India will open a new Fast Trak lab.

India's biotechnology industry, estimated to reach 150 billion dollars by 2025, expects to see the number of emerging biotech companies' boom from 3,475 to more than 10,000.

The State of Telangana has a rich mix of global pharmaceutical companies, Indian local biopharma giants, and biotech startups. Combined, they contribute about 35% of India's pharmaceutical production.

This partnership enables us to share our global knowledge and expertise at a regional level. It is a new milestone in our continued investment in the India market and another way we fully support the growth of the industry.

Source: indiaeducationdiary.in

PHARMA INDIA

3. Alembic pharma get novel drug for Indian cancer patients

US FDA has approved Rhizen Pharmaceutical's novel next-generation PI3K-delta inhibitor Umbralisib for the treatment of refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 based regimen and relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.

Fifty% ownership of Rhizen Pharmaceuticals with Vadodara based Alembic Pharma. Umbralisib is a novel, next-generation, oral, once-daily, inhibitor of phosphoinositide 3 kinase delta and casein kinase 1 epsilon and was discovered by Rhizen Pharma and subsequently licensed to TG Therapeutics in 2012.

Source: pharmabiz.com

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PHARMA INDIA

4. USFDA approved granules India's potassium chloride capsules

Granules India has received USFDA approval for abbreviated new drug application (ANDA) for potassium chloride extended-release capsules USP (600 mg) and 750 mg.

The product would be manufactured at the company's Hyderabad facility and it is expected to be launched shortly.

Potassium chloride is indicated for the treatment of patients with hypokalemia with or without metabolic alkalosis, in digitalis intoxications, and in patients with hypokalemic familial periodic paralysis.

It is also indicated for the prevention of hypokalemia in patients who would be at particular risk if hypokalemia were to develop e.g., digitalized patients or patients with significant cardiac arrhythmias, hepatic cirrhosis with ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, and certain diarrheal states.

Granules India is a growing pharmaceutical manufacturing company. The company produces finished dosages (FDs), pharmaceutical formulation intermediates (PFIs) and active pharmaceutical ingredients (APIs).

Source: business-standard.com

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REGULATORY ROUND-UP

1. New toolbox for EMA's PRIME designees

The European Medicines Agency has released a draft guidance to guide drug developers using its Priority Medicines (PRIME) scheme to accelerate authorization of new therapies.

The guidance comes in the form of a toolbox that pulls together existing regulatory tools and scientific guidance for sponsors of medicines holding the PRIME designation.

EMA hopes to support PRIME applicants in speedier and more complete filings of Module 3 quality data packages, thus smoothing the path for marketing authorization of these therapies, which address currently unmet medical needs.

Source: raps.org

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REGULATORY ROUND-UP

2. Essential diagnostics list updated for COVID-19

The World Health Organization has updated list of essential diagnostics for 2021 to include recommendations for polymerase chain reaction and antigen-based diagnostic tests for COVID-19.

WHO has also recommended additional tests that detect disease preventable by vaccines and other infectious diseases, as well as more tests for such non-communicable diseases as cancer and diabetes. New endocrine tests are also on the list to address reproductive and women's health needs.

In all countries, the use of appropriate diagnostic tests can help inform evidence-based treatment and responsible use of medicines, resulting in improved allocation of resources and better health outcomes.

Source: raps.org

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REGULATORY ROUND-UP

3. EMA consults on revised risk minimization module

The European Medicines Agency has released draft versions of the third revision to its good pharmacovigilance practice module XVI guideline on risk minimization measures and its second addition to the guideline on methods for evaluating the effectiveness of risk minimization measures for public consultation.

Two GVP documents are meant to clarify and enhance tools for risk minimization measures and strengthen methods for studying the effectiveness of the implementation of risk minimization measures and the possible need for adjustments of risk minimization measures in the interest of patient safety.

Updates included clarifications about the role of risk minimization for risk management planning and the impact on the risk-benefit balance of medicinal products.

Three new sections include guidance on applying and requesting additional risk minimization measures, the role of risk communication, dissemination and implementation and the addition of risk minimization measures within the lifecycle of product.

Source: raps.org

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REGULATORY ROUND-UP

4. Updates on COVID vaccine pharmacovigilance

The European Medicines Agency's safety committee review data from clinical use of the COVID-19 messenger RNA (mRNA) vaccine co-developed by Moderna and the US National Institutes of Health.

According to the EMA report PRAC requested the marketing authorization holder to continue reviewing all anaphylaxis cases for further assessment by the committee as part of the assessment of the company's upcoming first Summary Monthly Safety Report.

The US investigation into the reported cluster did not reveal quality problems with the vaccine, and US regulators permitted vaccinations to continue from the vaccine lot in question.

PRAC concurred with the US Centers for Disease Control and Prevention (CDC), which calculated an anaphylaxis rate of 2.5 individuals per million vaccine doses administered for the Moderna vaccine.

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Piramal pharma has completed acquisition of CCPL

Piramal Enterprises is one of India's large diversified companies with presence in financial services and pharmaceuticals.

Piramal Pharma has completed the acquisition of Convergence Chemicals on 24 February 2021.

Piramal Pharma will acquire additional stake in Convergence Chemicals for an aggregate cash consideration of Rs 65.10 crore. Piramal Enterprises' net profit jumped 10.4% to Rs 799.39 crore on 3.1% decline in net sales at Rs 3,168.61 crore in Q3 December 2020 over Q3 December 2019.

Source: business-standard.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Novartis to support Pfizer-BioNTech for vaccine production

Novartis has signed an agreement with Pfizer and BioNTech's Covid-19 vaccine by leveraging its manufacturing capacity and capabilities to fight the Covid-19 pandemic.

According to the agreement, Novartis will obtain bulk mRNA active ingredient from BioNTech and fill this into vials under aseptic conditions.

In Stein, Switzerland the company will use its aseptic manufacturing facilities. It will be sent for shipment to BioNTech for delivery to healthcare system customers across the globe.

On final agreement, Novartis will initiate production at its plant in Stein with the delivery of initial shipment expected in the third quarter.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. ICON to acquire PRA health sciences

ICON is a global provider of outsourced drug and device development and commercialization public health organizations has acquired PRA Health Sciences. The consideration represents an approximately 30% premium to PRA's closing price as of 23rd February 2021.

The transaction brings together growing organizations with similar cultures and a shared focus on high quality and efficient clinical trial execution from Phase 1 to post-approval studies.

The transaction is anticipated to be highly accretive delivering double-digit accretion in the first full year and growing to 20%+ thereafter, driven by growth momentum, estimated annual run-rate cost synergies of $150 million, and the combined effective tax rate decreasing to 14%, both to be realized in approximately 4 years.

Source: europeanpharmaceuticalreview.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. Wavelength pharmaceuticals acquires Vanamali

Israel-based developer and manufacturer Wavelength Pharmaceuticals has acquired a majority stake in Vanamali Organics Pvt. Ltd. of Telangana, India.

Vanamali manufactures pharmaceutical key starting materials and advanced drug intermediates. The deal expands Wavelength's drug substance manufacturing footprint and its API contract development and manufacturing organization (CDMO) business.

Vanamali Organics' manufacturing capability ranges from small research quantities up to multi-ton commercial-scale production.

Source: pharmtech.com

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DRUGS: APPROVALS AND LAUNCHES

1. Centessa Pharmaceuticals launches new kind of pharmaceutical R&D model

Centessa Pharmaceuticals has launched a novel asset-centric pharmaceutical company designed and built to advance a portfolio of highly validated programs.

In conjunction with its launch, Centessa has completed the merger of 10 private biotech companies that will each continue to develop its assets with oversight from the Centessa management team.

Centessa is to build a unique operational framework that aims to reduce some of the key R&D inefficiencies that classical pharmaceutical companies face because of structural constraints.

Source: businesswire.com

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DRUGS: APPROVALS AND LAUNCHES

2. DCGI has approved Sun Pharma's Brevipil for epilepsy treatment

DCGI has approved an adjunctive therapy (Brivaracetam) in the treatment of partial-onset seizures in patients. Sun Pharma's Brevipil (Brivaracetam) tablet 25 mg/50 mg/75 mg/100 mg was launched in the market on February 21, 2021.

An over the next few weeks, Brevipil oral solution and injectable will be available in the market.

Brivaracetam belongs to the class of anti-epileptic drugs. It has fast onset of action and promising efficacy. Brivaracetam is sustained with favorable tolerability and compliance to the treatment.

Source: livemint.com

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DRUGS: APPROVALS AND LAUNCHES

3. USFDA issues emergency use for Janssen COVID-19 Vaccine

U.S. Food and Drug Administration has approved an emergency use for the third vaccine (Janssen COVID-19 Vaccine) for the prevention of coronavirus disease 2019 (COVID-19).

The EUA allows the Janssen COVID-19 Vaccine to be distributed in the U.S for use in individuals 18 years of age and older.

The Janssen COVID-19 Vaccine is manufactured using a specific type of virus called adenovirus type 26 (Ad26). The vaccine uses Ad26 to deliver a piece of the DNA or genetic material that is used to make the distinctive “spike” protein of the SARS-CoV-2 virus.

After receiving vaccine the body can temporarily make the spike protein, which does not cause disease, but triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2.

Source: fda.gov

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DRUGS: APPROVALS AND LAUNCHES

4. Natco pharma recieved approval for CTPR

Natco Pharma received approval for chlorantraniliprole (CTPR)-1st key product of crop health sciences division. The company announced the approval of registration by the Central Insecticide Board & Registration Committee (CIB&RC) for indigenous manufacture of chlorantraniliprole (CTPR) Technical.

CTPR technical is formulated into broad-spectrum insecticides used in several crops for better pest management. The active ingredient is used across products commercialized by FMC under its brands Coragen and Ferterra.

NATCO would be the 1st indigenous manufacturer of this technical product.

Source: pharmatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. BioNTech COVID-19 vaccine developed with Pfizer

Pfizer
Working together for a healthier world™

BioNTech has developed BNT162 vaccine using mRNA technology with the partnership of Pfizer.

To expand its production capacity, the manufacturing site was acquired by BioNTech from Swiss pharma company Novartis in September 2020.

The site will be the largest mRNA manufacturing facilities worldwide. Expected to produce up to 750 million doses of the Covid-19 vaccine.

Source: europeanpharmaceuticalreview.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. PaxMedica's PAX-101 improves core symptoms of autism

The Phase II randomized, double-blind and placebo-controlled trial was conducted. It evaluated the safety and efficacy of PAX-101 in 52 South African patients diagnosed with moderate to severe autism spectrum disorder.

PaxMedica has developed PAX-101 (IV suramin), an investigational drug being as a potential treatment for the core symptoms of autism spectrum disorder (ASD) in Phase II trial.

The results from this clinical trial demonstrate promise for advancing this novel treatment into the next phase of development.

There is an enormous unmet need in treating the symptoms of moderate to severe ASD, which include both social and communication challenges as well as restrictive, repetitive behaviors. PAX-101 has the potential clinical improvements in this debilitating condition, which could positively impact the lives of many families.

Additionally, at Week 14, patients treated with PAX-101 also demonstrated a mean improvement from baseline in the CGI-I overall symptom severity score of 0.9 points versus 0.4 on placebo, representing a clinically meaningful change from baseline.

PAX-101 were shown to be safe and tolerable throughout the 14 weeks of treatment. The most common treatment-emergent adverse events in the treatment groups were rash, upper respiratory infection and vomiting. There was one serious adverse event in a patient on PAX-101 with multiple concomitant conditions that resolved following acute treatment.

Source: europeanpharmaceuticalreview.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Semaglutide for treatment of obesity

The large-scale international trial was conducted to evaluate semaglutide for treating obesity cuts body weight. The study has been published in the New England Journal for Medicine.

The drug semaglutide, works by hijacking the body's own appetite regulating system in the brain leading to reduced hunger and calorie intake.

The findings of this study represent improving the health of people with obesity. Seventy five % of people who received semaglutide. No other drug has come close to producing this level of weight.

Semaglutide is already approved and used clinically at a lower dose for treatment of diabetes. Semaglutide has been submitted for regulatory approval as a treatment for obesity to the NICE, the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).

Source: sciencedaily.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. Phase III trial for Bharat Biotech's BBV152 Covaxin

Bharat Biotech has developing vaccines for infectious diseases, announced the first interim analysis of its BBV152 Covaxin. Covid-19 vaccine candidate demonstrated an interim vaccine efficacy of 81% in its phase 3 clinical trial.

In this clinical trials involved 25,800 subjects, the largest ever conducted in India.

Result shown high clinical efficacy against Covid-19 but also significant immunogenicity against the rapidly emerging variants. BBV152 contains a whole virion inactivated SARS-CoV-2 vaccine, which is produced in vero cells. It is stable at 2 to 8°C and is shipped in a ready-to-use liquid formulation that permits distribution using existing vaccine supply chain channels.

BBV152 has a 28-day open vial policy as a unique product characteristic, thus reducing vaccine wastage by approximately 10-30%.

The interim analysis included a preliminary review of the safety database, which showed that severe, serious, and medically attended adverse events occurred at low levels and were balanced between vaccine and placebo groups. The trial's conduct and monitoring are as per Good Clinical Practice guidelines

Source: pharmabiz.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Regeneron, Sanofi score again in patent fight with Amgen

Once again courts judgment with Sanofi and Regeneron's favor against Amgen's years-long PCSK9 patent.

First Amgen sued in 2014 alleging infringement. The sides took the case to trial in March 2016, and a jury favored Amgen, forcing Regeneron and Sanofi to pull Praluent from the key U.S. market.

Later, the federal appeals court found procedural errors and sent the case back for a new trial, where a jury upheld certain Amgen patent claims and tossed others aside. Amgen demanded an injunction to keep Praluent off the market, while Sanofi and Regeneron asked trial judge to overturn the jury's verdict. The judge sided with Sanofi and Regeneron.

Source: thepharmaletter.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. An innovator product Brivaracetam patent expired

An innovator product Brivaracetam patent has been expired on February 21, 2021, after that Sun Pharma's brand, Brevipil (Brivaracetam) tablet 25 mg/50 mg/75 mg/100 mg was launched in the market.

Sun Pharmaceutical has recently introduce the complete range of Brivaracetam dosage forms at an affordable price for epilepsy treatment in India.

Drugs Controller General of India (DCGI) has approved Brivaracetam as an adjunctive therapy in treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.

Brivaracetam belongs to the class of anti-epileptic drugs (AEDs) which have a unique or different mechanism of studies indicate that the response obtained with the use of Brivaracetam is sustained, with favourable tolerability profile and compliance to the treatment.

Source: medicaldialogues.in/news

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Eagle pharmaceuticals receives additional FDA questions

U.S. Food and Drug Administration has issued a complete response letter for its Abbreviated New Drug Application for vasopressin. Eagle has completed an extensive amount of developmental work and continues to do so for its first-to-file polypeptide, where brand sales of the product are over $700 million annually.

Eagle believes it can fully respond to the questions raised. There is one additional short duration study that will need to be completed and analyzed.

In other vasopressin news, the patent case against Endo Par Innovation Company, LLC is now scheduled to begin on July 7, 2021. Eagle remains confident about this litigation. Par's asserted patents claim a formulation with a pH of 3.7-3.9.

Eagle's proposed ANDA product specifies a pH outside of that range. The Company is confident that its ANDA will be approved in a reasonable timeframe.

Source: businesswire.com/news

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Federal circuit upholds Takeda patent

In 2017, Takeda sued Torrent and Indoco in New Jersey federal court, seeking to block their proposed generic versions of the drugs. Following a consolidated bench trial, U.S. District Judge found Takeda's alogliptin patent valid and infringed, and the defendants appealed.

Torrent argued that the patent was obvious because a person of ordinary skill in the art would have known to make the patent substance through modifications to a previously known, and patented, compound called F162.

A federal appeals court has upheld Takeda Pharmaceutical Co Ltd's patent on the active ingredient in its Type II diabetes drugs.

Finally, a federal Judge rejected both companies' arguments that the district court wrongly ignored their argument that, for the purposes of evaluating the patent.

Source: reuters.com

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TECHNOLOGY /NDDS

1. Wireless smart catheter for bladder control

A medtech company, has developed a wireless urinary catheter (IntelliFlow Bladder management system), that can be controlled with the remote control.

Currently, patients with urinary retention may have to use up to 200 disposable urinary catheters a month and also cause complications, including infection. It can also be expensive, to address thease problem, UroDev Medical has created the Intelliflow.

The catheter can reside in place for a week, A magnetic valve pump within can be opened to allow for urination, and then close using a wireless controller outside the body. The pump actively dispels urine from the bladder to allow for more complete emptying.

Source: medgadget.com

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TECHNOLOGY /NDDS

2. FDA approved clearFit cranial implant

FDA has approved ClearFit cranial implant for post-surgery ultrasound imaging. After brain surgery, the clear implants are used for cranial reconstruction and are custom-made for each patient. The company uses patient CT scans and 3D printing to produce the custom implants, and then sends the sterile constructs directly to surgeons.

Ultrasound imaging of the brain is not possible in adults due to properties of the skull. The implants allow clinicians to perform this task by being nearly transparent to ultrasound, and avoid other imaging modalities which cause radiation exposure to patients.

The aim of the implants to restore the natural contours of the skull while maintaining the required functionality of such a device, including the required mechanical properties and ease of visualization of the underlying tissue.

Source: medgadget.com

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TECHNOLOGY /NDDS

3. FDA approved 12 megapixel display breast imaging

A Plymouth, MN company has released an impressive 12 megapixel monitor intended for use in breast imaging. The FDA cleared display comes with a high-speed graphics controller for Tomo image processing, as well as Double Black Imaging's own comprehensive calibration software.

At 31 inches in size, the Gemini 12MP can be used instead of two separate 5 megapixel monitors that are now ubiquitous in radiologic imaging.

Two different mammography or tomography exams can be easily compared using one screen without the distracting plastic bezel in between.

Source: medgadget.com

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TECHNOLOGY /NDDS

4. FDA approved neuromuscular tongue stimulator

The FDA has authorized via the *De Novo* process that trains the muscles around the tongue to become stronger in order to reduce snoring and help alleviate OSA.

The device has a mouthpiece with four electrodes that are positioned around the tongue. The electrodes deliver electrical muscle stimulation, similar to transcutaneous electrical nerve stimulation (TENS), but to the area around the lower tongue. Strengthened muscles end up preventing the closing of the airway, allowing for the free movement of air in and out of the lungs.

This can be done at home or anytime the patient doesn't want to look silly using the device around strangers. This technology is not for everyone, including people with pacemakers, dental implants, people with OSA with an Apnea-Hypopnea Index of 15 or higher.

Source: medgadget.com

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