October 2012

Orthopedic Intelligence

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Inside This Issue

Q3-2012 Orthopedic Intelligence Posts

Are You Ready (for UDI)?

Sep.18.2012

by Patrick Biggins

FDA has released the long-awaited proposed final rule for implementation of the unique device identification (UDI) regulation passed by Congress in 2007. The initial 60-day comment period began on July 10, 2012. FDA has extended the comment period until October 25, 2012. Quoted from the Federal Register, Volume 77, Issue 180, "The Agency has received requests for a 45-day extension of the comment period for the information collection. Each request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the information collection." The proposed rule can be found and comments provided to FDA **here.**

The proposed rule further states, "Under the proposed system, the health care community and the public would be able to identify a device through a UDI that will appear on the label and package of a device. The UDI will provide a key to obtain critical information from a new database, the Global Unique Device Identification Database (GUDID), which will include information important to the identification of devices." UDI is based on automatic identification and data capture (AIDC) technology and will follow established international technical standards. The standards are included in the proposed new 21 CFR Part 830, Unique Device Identification.

So what is UDI? Simply stated, on the FDA website, "A UDI is a unique numeric or alphanumeric code that includes a device identifier, which is specific to a device model, and a production identifier, which includes the current production information for that specific device, such as the lot or batch number, the serial number and/or expiration date."

And lastly, why this posting asks are you ready? The proposed revision of 21 CFR Part 801 – Labeling, has the following information on the effectiveness of when UDI must be on devices after the publication date of the final rule:

- Class III medical device or a device licensed under the Public Health Service
- Class II – 3 Years
- Class I and devices not classified – 5 Years

The bottom line – FDA has issued a proposed final rule and is expecting industry to be ready to comply with the regulation once it is final.

FDA Regulation of Cellular Products Generated from a Patient's Own Cells

Aug.13.2012

by Kevin McGowan, Ph.D.

On August 7, 2012, the Wall Street Journal posted an opinion piece entitled, "The FDA Wants to Regulate Your Cells". In this article, the authors cite a decision 2 weeks ago in US District Court where the FDA had sued Regenerative Sciences, LLC, to cease providing stem-cell based treatments due to lack of marketing approval. The US District Court agreed with the FDA in this litigation.

In the United States, human tissue products are generally exempt from premarket review by the FDA, provided they meet certain requirements. One of these requirements is that the tissues be "minimally manipulated". Examples of human tissue that meets the "minimally manipulated" standard include organ transplants, blood transplants, allograft bone processed to remove lipids and cells, bone demineralized via acid treatment, and production of autologous platelet rich plasma (PRP) using a centrifuge for bed-side treatment. As such, all of these treatments are exempt from FDA pre-market review, except the centrifuge that produces the PRP.

However, the process used by Regenerative Sciences is described as follows:

"This procedure, called the RegenexxTM procedure, is used to treat certain orthopedic conditions, such as osteoarthritis, nonhealing bone fractures, avascular necrosis and bulging lumbar discs. In this procedure, the physician takes bone marrow from the patient's hip or synovial fluid from the patient's knee, as well as blood from the patient, and transports these materials to a nearby laboratory facility.

At this facility, mesenchymal stem cells are isolated from the bone marrow or synovial fluid and expanded in culture for two to three weeks using growth factors from the patient's blood, as well as other chemical reagents. The cells are then combined with drug products, such as doxycycline, which have been previously approved by the FDA, and are then transported back to the clinic for injection into the patient."

The district court sided with the FDA in deciding that process Regenerative Sciences utilized for processing the cells fell beyond the scope of "minimal manipulation".

However, FDA's view that these processing methods fall beyond the scope of "minimal manipulation" is not new. Genzyme's Carticel, FDA approved under a Biologics Licensing Application (BLA) since 1997, is a procedure similar to

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the one outlined by Regenerative Sciences. Carticel is produced by isolating a small portion of a patient's knee cartilage, from which the patient's cells are isolated, expanded in cell culture, and re-injected into the patient.

In particular, the expansion of cells, which involves the addition of many reagents and growth factors in a sterile environment, is the key step that takes the production process beyond minimal manipulation. Many chemical entities are added to stimulate the cells to divide and grow to obtain enough cells for therapeutic success. These processes, as demonstrated by laboratory science, can change the nature of the cells such that they are not necessarily the same as the ones removed from the patient. While these changes could be beneficial in some circumstances (such as increased ability to repair damaged tissues in the body), there is inherent risk that the cells could cause an adverse reaction in the patient due to these changes to the cells. In FDA's view, these treatments should be held to the same standards of safety and effectiveness as drugs and medical devices prior to use. **Read More**

More Rigorous FDA PMA Review Processes Are Here to Stay

Jul.6.2012

by Lee Ouyang

The FDA is charged with ensuring that the new medical devices it allows onto the market in the United States are **safe and effective**, and can reach the public in a **timely** way. By statute, safety and effectiveness must be based on **valid scientific evidence**. However, the FDA is not necessarily responsible for ensuring that the process is cost-effective when companies are working to prove that their devices will produce clinically significant results when used for their intended purposes. It is a necessarily tough process that can be expensive and time consuming, but there are some considerations that can be taken into account to mitigate the difficulty of getting a new device to market.

An examination of the orthopedic and spine PMAs shows that approvals can typically take an average of 26 months, but range anywhere from 9 to 42 months. (However, there are outliers. In 2009, one hip device was cleared after 74 months of review.) To further break it down, spine approvals averaged 18.3 months in review, while the orthopedic approvals averaged 29.6 months in review. Additionally, the review times have been trending higher in recent years, while the number of cleared PMAs has grown smaller at the same time.

The reason for this is that the standards for clinical evidence have been growing more stringent over the past 10 years. Up to 2006, the approval process simply focused on the following questions:

- Did you "win" the study by demonstrating non-inferiority?
- Was the proper indication studied, and was the control group correctly matched to the treatment group?
- Was patient accountability high?
- Was a simple, but proper, statistical plan utilized?
- Were adverse events understood, and is a plan to mitigate them properly implemented?
- Were there quality study sites?
- Are good manufacturing processes in place?

When comparing spine and general orthopedic PMA approval timelines, it is clear that the answers to these questions play a large role in affecting outcomes. A side-by-side comparison of some areas where these PMAs differ is revealing:

	Spine	General Orthopedic
Patient Accountability	All greater than 90%	Typically less than 85%
Investigational Patient Sample Size	More than 200 patients	Less than 200 patients
Study Design	Multicenter, prospective, randomized, controlled	Fewer follow-up time points, single-arm, non-random
Outcome Measures	Common set of outcome measurement tools utilized	Different anatomies necessiate varied outcome measurement tools

Newer PMA applications also are seeing a greater rigor, which has already been reflected in many of the spine PMAs approved by the FDA, thus explaining why spine PMAs have a smaller average review time. The agency now demands a greater emphasis on:

- Data analysis independence- elimination of bias
- Study safety measures- implementation of stopping rules
- Radiographic protocol- determine what is happening at the biomechanical level
- Good manufacturing processes- scrutiny of cleaning and sterilization processes
- New concerns- materials, radiographic "safety", and mechanism of action

There are also more detailed risk-benefit determinations. Reviewers now expect peri-operative measurements, amongst other metrics, as part of the data package accompanying PMA applications. This is simply because the FDA is seeking the highest scientific rigor, in order to maximize patient safety. **Read More**

Q3-2012 Top Orthopedic Roundup Today News Articles

Clinical, Regulatory, IP, Compliance, Reimbursement

1. Smith & Nephew introduces pioneering new fixation devices and techniques for hip arthroscopy at ISHA meeting
2. Amedica Receives FDA 510(k) Clearance For A Second Generation Interbody Fusion Device System
3. Globus Medical Announces Its First PMA Approval for the SECURE®-C Cervical Artificial Disc
4. Court reverses ruling against NuVasive in trademark suit
5. LDR Announces FDA Clearance of the Avenue® L Lateral Lumbar Cage System
6. Maryland considers complete overhaul of payment system to doctors, hospital
7. SpineFrontier, Inc. Receives a Warning Letter from the FDA

8. J&J recalls Synthes bone putty due to fire risk, FDA Website
9. FDA Proposes Criteria for Determining Completeness of 510(k) Submissions
10. TiGenix completes patient enrollment in Phase IIa rheumatoid arthritis study
11. Life Spine Awarded Fourth Patent Regarding Its Interspinous Portfolio
12. NovaBone Putty USA Patent Allowed
13. Spinal Restoration, Inc. Completes Enrollment of the Phase III Study of the Biostat® System
14. Integrity Life Sciences Receives US FDA 510(k) Clearance for its Integrity Spinal Care System Medical Device
15. FDA to Release Plan for Device Identification System

Finance, M&A & Other Corporate Transactions

1. Alphatec Spine Receives Board Approval to Acquire Assets of Phygen, LLC
2. Medtronic Signs Agreement to Acquire China Kanghui Holdings
3. IlluminOss Medical Secures $28 Million Series C Financing for Minimally Invasive Bone Fracture Repair
4. Medical device startup, IntelliRad Control, raises $5.3 million to reduce radiation in medical procedures
5. CONMED Corporation Completes Tender Offer for All Outstanding Shares of Viking Systems, Inc.
6. BONESUPPORT Announces Exclusive Supply And Distribution Agreement With Biomet, Inc. For BONESUPPORT's Proprietary CERAMENT™|BONE VOID FILLER
7. Sectra initiates cooperation with Zimmer for orthopaedic surgery
8. Nextremity Solutions Closes Funding of $6.6 Million and Announces Opening of First Preferred Round
9. Globus Medical Announces Pricing of Initial Public Offering
10. Nextremity Solutions, Inc. Signs Product Development and Distribution Agreement with Z-Medical GmbH
11. Nottingham scientists win £1.2M grant for research into engineering of nanomaterials
12. Teleflex Signs Definitive Agreement to Sell OEM Orthopedics Business for $45.2 Million
13. Conmed Healthcare to be acquired for $59M by Correct Care
14. iWalk gets $3M, launches BiOM for more amputees
15. Benvenue Medical Secures $25 Million Series D Financing

Technology, Product & Industry

1. DePuy Mitek Launches ENDURANCE™ Hip Solutions
2. Anterior Hip Replacement a Safer, More Natural Option, According to Leading Orthopedic Surgeons at Arizona Orthopaedic Associates
3. FzioMed Announces 300,000 Units of Oxiplex Sold
4. DFINE Announces Full U.S. Commercial Release of STAR Tumor Ablation System
5. Ascendx Spine™ Begins Commercialization in Europe
6. Alphatec Spine Launches New MIS Device, the BridgePoint(TM) Spinous Process Fixation System
7. Composite Nanofibers Open Next Chapter in Orthopaedic Biomaterials
8. Interventional Spine Announces its 75th Patient Treated with the PerX360 Percutaneous Spinal Fusion Technology
9. Bonovo® Orthopedics, Inc. Launches the First PEEK Lateral Interbody Fusion Cage in China
10. Neurotech Releases New Back Pain Device
11. TiGenix signs up 4th major hospital in the Netherlands for innovative cartilage repair therapy
12. Older Hip Implant, Knee Replacement Patients Face Heart Attack Risk Following Surgery
13. Blue Belt Technologies Announces World's First Surgery Performed with NavioPFS™ Robotic Surgical System
14. Over 3,000 Patients Treated with iFuse® for Minimally Invasive Surgical Sacroiliac Joint Fusion
15. Stryker Initiates Voluntary Product Recall of Modular-Neck Stems

Operational, HR & Other

1. Mindray Medical Sees Lucrative Growth in China Orthopedics
2. RTI Biologics donates BioSet RT Allograft Paste implants to CURE International
3. Chronic pain may cost U.S. $635 billion a year
4. Paradigm Spine Welcomes Hallett Mathews, MD, MBA As Its Executive Vice President & Chief Medical Officer
5. Medtronic to cut another 500 jobs in hopes of saving $125M per year
6. Medical tax stirs debate over artificial joints
7. Shu-Tung Li, Founder and CEO of Collagen Matrix, Inc. Selected for Induction into the New Jersey Inventors Hall of Fame
8. Medtronic's China strategy involves a shopping spree. Are these firms targets?
9. Hip: Feds probe Wright Medical's Profemur metal hip implants
10. The Affordable Care Act: Implications for Emerging Med Tech Companies
11. Top-Ranked Hospitals for Orthopedics
12. Lanx loses bid to toss NuVasive's poaching lawsuit
13. Conmed Healthcare Management, Inc. Board of Directors Under Investigation for Potential Breaches of Fiduciary Duty by Glancy Binkow & Goldberg LLP
14. VEXIM : Continues to Develop Its Business across Europe by Setting up an Italian Subsidiary
15. Orthofix settles Mexico bribery beef for $7.4M, avoids criminal charges

Search the 510(k) Premarket Notification Database for more information on the below clearances

Q3-2012 Orthopedic Panel 510(k) Clearances

Joint

Device Name	Applicant	510(k) #	Decision Date
mpact extension16	medacta international	K12264117	9/28/12
gmk narrow18	medacta international	K12223219	9/28/12
itotal cruciate retaining (cr) knee repl24	conformis, inc.	K12203325	9/27/12
bencox foret & bencox delta30	corentec co., ltd	K12166531	9/25/12

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Joint

Device Name	Applicant	510(k) #	Decision Date
speedlock hip knotless fixation implant 32	arthrocare corporation	K12094333	9/21/12
mets modular proximal femur38	stanmore implants worldwide ltd.	K12105639	9/20/12
mets modular total femur52	stanmore implants worldwide ltd.	K12105553	9/19/12
mets modular distal femur54	stanmore implants worldwide ltd	K12102955	9/19/12
oxford ankle fusion nail(afn) system62	ortho solutions limited	K12157563	9/14/12
corin metafix hip stem64	corin u.s.a.	K12143965	9/14/12
zmr hip system kwz-prosthesis, hip, con66	zimmer, inc.	K11329667	9/14/12
unity toatal knee system78	corin u.s.a.	K11306079	9/10/12
taperset hip small stems80	consensus orthopedics, inc.	K12193581	9/10/12
bencox mirabo cup bencox mirabo insert (82	corentec co., ltd	K12092483	9/10/12
smith & nephew, inc. shoulder system ins86	smith & nephew, inc.	K12171487	9/7/12
depuy cta reverse shoulder system88	depuy france	K12244289	9/6/12
conformis iuni unicondylar knee replacem90	conformis, inc.	K12197491	9/6/12
mets smiles total knee replacement96	stanmore implants worldwide ltd	K12099297	9/5/12
ioi total hip102	iconacy orthopedic implants, llc	K121034103	9/4/12
sl-plus mia femoral stems with ti/ha coa122	smith & nephew, inc.	K122296123	8/28/12
zimmer trabecular metal total ankle132	zimmer, inc.	K120906133	8/24/12
polarcup dual mobility system136	smith & nephew, inc.	K122244137	8/23/12
taperloc complete size 4mm and xr 123154	biomet manufacturing corp.	K120030155	8/17/12
movation knee system162	encore medical, l.p.	K121727163	8/15/12
journey ii cr knee system166	smith & nephew, inc.	K121443167	8/13/12
profemur z revision hip stem176	wright medical technology, inc.	K121221177	8/9/12
smith & nephew, inc. total knee system i184	smith & nephew, inc.	K121393185	8/7/12
hip systems194	howmedica osteonics corp	K121308195	7/30/12
dynasty biofoam shell196	wright medical technology, inc.	K121544197	7/30/12

Joint

Device Name	Applicant	510(k) #	Decision Date
vega knee system200	aesculap implant systems	K121879201	7/27/12
comprehensive reverse shoulder - e1 poly210	biomet corporation	K121183211	7/26/12
hls uni evolution & u-kneetec218	tornier, inc.	K120262219	7/25/12
domed tri-peg patella, highly cross link222	encore medical, l.p.	K121835223	7/20/12
gmk sphere224	medacta international	K121416225	7/20/12
sl-plus standard and lateral femoral ste230	smith & nephew, inc.	K120211231	7/19/12
u2 acetabular cup, plasma spray242	united orthopedic corp.	K121777243	7/18/12
arrow reverse shoulder system254	fournitures hospitalieres industrie	K112193255	7/12/12
seviin reverse shoulder258	ingen orthopedics llc	K120374259	7/9/12
aequalis adjustable modular reverse shou266	tornier, inc.	K120739267	7/5/12

Spine

Device Name	Applicant	510(k) #	Decision Date
cd horizon spinal system20	medtronic sofamor danek, inc.	K12243321	9/28/12
oracle lumbar intervertebral body fusion26	accel spine	K12156727	9/26/12
dali spinal fixation system34	accel spine	K12156835	9/21/12
sterispine lc cage36	safe orthopaedics	K12202137	9/20/12
choice spine fixation system40	choice spine, lp	K12185041	9/20/12
nextgen altius oct system42	biomet spine (aka ebi, llc)	K12237843	9/20/12
enduramesh50	lucero medical, llc	K12262251	9/19/12
clydesdale spinal system56	medtronic sofamor danek, inc.	K12259157	9/18/12
van gogh anterior cervical plate system70	accel spine	K12107871	9/13/12
quintex cervical plating system72	aesculap implant systems, llc	K12180173	9/11/12
range spinal system74	k2m, inc.	K12163075	9/11/12
nuvasive precept spinal system76	nuvasive, inc.	K12235277	9/11/12

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Spine

Device Name	Applicant	510(k) #	Decision Date
lanx spinal fization system84	lanx, inc.	K12131685	9/10/12
reliance anterior cervical plate system100	reliance medical systems, llc	K122216101	9/5/12
alamo p104	alliance partners, llc	K122047105	9/4/12
stalif c108	centinel spine, inc.	K120819109	8/31/12
cervical cage110	eisertech, llc	K122444111	8/30/12
staxx xd system114	spine wave, inc.	K121889115	8/29/12
capstone spinal system116	medtronic sofamor danek usa, inc.	K121760117	8/29/12
neuro vention laminplasty plating system118	neurovention llc	K121276119	8/29/12
tetris ii120	signus medizintechnik gmbh	K122317121	8/29/12
xia 3 spinal system124	stryker spine	K113666125	8/28/12
instrument system for endoscopic spinal 126	theken spine llc	K121482127	8/28/12
ldr spine usa spine tune, tl spinal syst128	ldr spine usa inc.	K121103129	8/24/12
phantom plus ceramic cage system130	amedica corp.	K121892131	8/24/12
nuvasive polyaxial spinal screws134	nuvasive, inc.	K121619135	8/24/12
trans1 interbody fusion system138	trans1 incorporated	K120991139	8/23/12
cd horizon spinal system142	medtronic sofamor danek, inc.	K121764143	8/21/12
avs as peek spacer144	stryker spine	K120486145	8/20/12
lanx spinal fixation system150	lanx, inc.	K122145151	8/17/12
stgc152	cardinal spine, llc	K121176153	8/17/12
spinevu endoscopic spine system (sess)156	spine view, inc.	K121548157	8/16/12
4cis vane spine system160	solco biomedical co., ltd.	K121615161	8/15/12
erisma-lp164	clariance	K120469165	8/13/12
c7 anterior cervical intervertebral fusi168	medyssey co., ltd.	K121320169	8/10/12
oracle mis spinal fixation system172	accel spine	K120714173	8/9/12

Spine

Device Name	Applicant	510(k) #	Decision Date
oracle posterior cervial fixation system174	accel spine	K121136175	8/9/12
espin178	nlt spine ltd	K120553179	8/9/12
reform pedicle screw system180	spinal usa	K121172181	8/8/12
nautilus spinal system182	life spine	K111953183	8/7/12
lanx spinal fixation system186	lanx, inc.	K121940187	8/2/12
synthes matrix system188	synthes spine	K120838189	7/31/12
spinal elements posterior cervical/thora190	spinal elements, inc.	K120467191	7/30/12
sterispineps pedicle screw, sterispineps192	safe orthopaedics	K121299193	7/30/12
matisse anterior cervical interbody fusi198	accel spine	K121569199	7/27/12
sovereign spinal system202	medtronic sofamor danek	K121982203	7/26/12
beacon stabilization system204	globus medical inc.	K121922205	7/26/12
ldr spine usa avenue l interbody fusion208	ldr spine usa inc.	K113285209	7/26/12
synthes zero-p variable angle (va)216	synthes spine co.lp	K121852217	7/25/12
casian, 3.5/4.5 connectors226	k2m, inc.	K121808227	7/20/12
orthofix acp (anterior cervical plate sy228	orthofix inc.	K121658229	7/20/12
m.u.s.t pedicle screw system232	medacta international	K121115233	7/18/12
medicrea international anterior lumbar p236	medicrea international	K121323237	7/18/12
pathfinder nxt minimally invasive pedicl240	zimmer spine, inc.	K121671241	7/18/12
nuvasive brigade anterior plate system246	nuvasive, inc.	K121837247	7/16/12
calypso system248	hogan lovells us llp	K120564249	7/16/12
infill intervertebral body fusion device252	pinnacle spine group, llc	K121733253	7/13/12
slimplicity solo anterior cervical plate256	spinal usa llc	K112748257	7/11/12
venus lumbar intervertebral body fusion 264	l & k biomed co., ltd	K121096265	7/6/12
cd horizon spinal system268	medtronic sofamor danek usa, inc.	K121680269	7/5/12
acculif tl cage270	coalign innovations, inc.	K121683271	7/5/12

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Spine

Device Name	Applicant	510(k) #	Decision Date
fortify integrated corpectomy spacers, (272	globus medical, inc.	K121107273	7/3/12
spine frontier indus acp system274	spinefrontier, inc.	K121060275	7/3/12
spinal elements cerclage system276	spinal elements, inc.	K120177277	7/3/12
depuy pulse lumbar cage system278	medos international sarl	K120966279	7/3/12

Trauma

Device Name	Applicant	510(k) #	Decision Date
pmt bone screws22	providence medical technology, inc.	K12171323	9/27/12
short lateral superior clavicle plate, l28	advanced orthopaedic solutions, inc.	K12262329	9/26/12
orthofix contours proimal humeral plate 44	orthofix srl	K12254145	9/20/12
viper and expedium navigated instruments46	medos international sarl	K12086747	9/20/12
biomet microfixation sternal closure sys48	biomet microfixation	K12130249	9/19/12
bicera (tm) resorbable bone substitute58	wiltrom corporation limited	K11094959	9/18/12
kmc kyphoplasty system60	shanghai kinetic medical co., ltd	K11374261	9/17/12
jazz system68	implanet s.a.	K12154169	9/13/12
maxlock extreme system92	orthohelix surgical designs, inc.	K12200593	9/6/12
loqteq large fragment set loqteq cortica94	aap implantate ag	K11364895	9/6/12
stryker sdc3 hd information management s98	stryker endoscopy	K12189399	9/5/12
orthofix galaxy fixation system106	orthofix srl	K113770107	9/4/12
loqteq small fragment set loqteq cortica112	aap implantate ag	K113652113	8/30/12
genesys pressft suture anchor140	linvatec corporation d/b/a conmed linvat	K121890141	8/22/12
samba screw, 9mm dia., 25mm long, sambia146	medical design llc.	K121148147	8/20/12
gridlock plating system148	trilliant surgical ltd	K121452149	8/20/12
altomec arthroscope158	altomec endoscopy inc	K112548159	8/15/12

Trauma

Device Name	Applicant	510(k) #	Decision Date
zimmer natural nail system cephalomedull170	zimmer gmbh	K120715171	8/10/12
stryker all suture anchors206	stryker	K120509207	7/26/12
pioneer sternal assist implant system212	pioneer surgical technology, inc	K120016213	7/26/12
hoffmann 3 modular external fixation sys214	stryker corp.	K121252215	7/25/12
surgicase connect, surgicase guide220	materialise n.v.	K112389221	7/20/12
xmcp, hallux, tarsx, extremity medical s234	extremity medical llc	K121417235	7/18/12
io fix, io fix plus, carpalfix, extremit238	extremity medical llc	K121349239	7/18/12
3.9mm reelx stt suture anchor system244	stryker corp.	K120824245	7/18/12
congruent bone plate system: acu-loc 2 p250	acumed llc	K120903251	7/13/12
synthes 2.7/3.5mm variable angle lcp ank260	synthes usa	K121601261	7/6/12
synthes multiloc humeral nailing system262	synthes usa products llc	K120807263	7/6/12

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Search the Premarket Approval (PMA) Database for more information on the below approvals

Q3-2012 Orthopedic Advisory PMA Approvals

Joint

Device Name	Applicant	PMA #	Decision Date
exactech novation ceramic ahs articulati19	exactech, inc.	P050039 S011	9/27/12
birmingham hip resurfacing (bhr) system21	smith & nephew, inc.	P040033 S018	9/11/12
reflection ceramic acetabular hip system22	smith & nephew, inc.	P030022 S022	9/6/12
duraloc option ceramic hip system23	depuy orthopaedics, inc.	P040023 S024	9/6/12
depuy ceramax ceramic total hip system24	depuy, inc.	P070026 S007	9/6/12
pinnacle complete acetabular hip system25	depuy orthopaedics, inc.	P090002 S005	9/6/12
exactech novation ceramic ahs articulati26	exactech, inc.	P050039 S010	8/24/12
exactech novation ceramic ahs articulati27	exactech, inc.	P050039 S008	8/17/12
oxford meniscal unicompartmental knee sy28	biomet, inc.	P010014 S037	8/15/12
nexgen lps-flex mobile and lps-mobile be29	zimmer, inc.	P060037 S018	8/10/12
oxford patial knee system35	biomet, inc.	P010014 S036	8/2/12
oxford partial knee system37	biomet, inc.	P010014 S035	7/19/12

Spine

Device Name	Applicant	PMA #	Decision Date
secure-c artificial cervical disc18	globus medical inc.	P100003	9/28/12
bryan cervical disc20	medtronic sofamor danek usa, inc.	P060023 S002	9/13/12
prodisc-l total disc replacement40	synthes spine	P050010 S012	7/10/12

Trauma

Device Name	Applicant	PMA #	Decision Date
ol1000/ol1000 sc and spinalogic bone gro30	dj orthopedics, llc	P910066 S026	8/10/12
infuse bone graft31	medtronic sofamor danek usa, inc.	P000054 S028	8/3/12
infuse bone graft32	medtronic sofamor danek usa, inc.	P000054 S030	8/3/12
infuse bone graft/lt cage lumbar tapered33	medtronic sofamor danek, inc.	P000058 S041	8/3/12
infuse bone graft/lt-cage lumbar tapered34	medtronic sofamor danek, inc.	P000058 S043	8/3/12
x-stop interspinous spacer system36	medtronic sofamor danek, inc.	P040001 S020	7/25/12
infuse bone graft38	medtronic sofamor danek usa, inc.	P000054 S033	7/17/12
infuse bone graft/lt-cage lumbar tapered39	medtronic sofamor danek, inc.	P000058 S048	7/17/12

About MCRA, LLC

MCRA was founded in 2004 and is the leading neuro-musculoskeletal consulting firm assisting companies at all stages of development, whether they are single-product companies or companies with several thousand technologies. MCRA provides "first-in-class" service to its clients through its superior knowledge base, global surgeon relationships and deeply experienced management team. The true value of MCRA is the integration of six business value creators—regulatory, reimbursement, clinical, intellectual property, quality assurance and healthcare compliance. MCRA's integration of these key value creating initiatives, as well as its focused specialization, creates unparalleled expertise to its clientele. For more information on MCRA please visit www.mcra.com.

About MCRA CRO

MCRA's unique Clinical Research Organization (CRO) enables international and US-based orthopedic companies of all sizes to successfully execute a clinical study. Our philosophy is to streamline the clinical trial process by utilizing our integrated approach to guide orthopedic device manufacturers through the medical device lifecycle. MCRA's expertise in the orthopedic industry is unmatched to our competition, while our cross-services integration is positioned to optimize quality, cost, and time. For more information on MCRA CRO please visit www.mcraCRO.com.