April 2012

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Inside This Issue

The Confusion of Interspinous Plates

Mar.21.2012

by Justin Eggleton

Interspinous plates have been a hot commodity lately as companies seek another fusion alternative. As hot as this area has been, it still remains fraught with regulatory difficulties due to lack of testing standards and an ever-changing regulatory pathway.

Testing issues have caused many companies to fumble towards the line of clearance. Since there are no testing standards, companies are left to develop their own protocols. While hours may be spent by a company making their protocols as scientific as possible, the company still needs to demonstrate the substantial equivalence of their device to a valid predicate device. Therefore, if their device is not tested in the same exact methodology used by a cleared device, demonstrating that the device is at least mechanically equivalent can be difficult if not impossible. Working with a testing lab or regulatory firm, like MCRA, who has experience with a lot of these devices is a better way to ensure the selected protocol yields data that can be compared to predicate devices.

Once testing is established and comparable, the regulatory pathway is just as complicated. Although there are a number of these devices on the market, FDA continues to gain a better insight on how to test these devices. As FDA learns more about how these devices behave, more questions are asked and companies are left figuring out next steps and how to perform additional testing requested by FDA.

These are still 510(k) devices, but the indications, intended use, design, and performance need to be equivalent to a predicate device. The easiest way to demonstrate equivalence is to conduct side by side testing and characterize the design of the device compared to predicates. If FDA thinks the device is different or a novel test method is used without comparison, clinical data can be requested.... **Read More**

CMS Takes a Closer Look at Hospital Infections to Drive Comparative Effectiveness Decision Making

Mar.9.2012

by Jaymie Petersen and Jeffrey D. Zigler, J.D.

On February 7, the Centers for Medicare & Medicaid Services (CMS) announced that new data on infection rates in inpatient facilities would inform healthcare utilization decision making by the Agency, via its *Hospital Compare* program. Information about central line-associated bloodstream infections (CLABSIs) will now be included for assessment of facilities around the nation performing services to Medicare beneficiaries, to help "save lives and cut costs." The Centers for Disease Control and Prevention (CDC) estimates that in 2009, there were about 41,000 CLABSIs in U.S. hospitals. Studies show that up to 25 percent of patients who get a CLABSI will die from the infection. Caring for a patient with a CLABSI adds about $17,000 to a hospitalization. These infections prolong hospitalizations and can cause death.

What does this mean for you?

Migrate your procedure out of the inpatient setting, if possible. If the surgical procedure supporting medical technology can be migrated away from the inpatient setting of care, to non-acute, outpatient care settings, manufacturers may avoid this issue, entirely. For those manufacturers or developers of medical technology who may be considering outpatient coverage strategy may be necessary, to help with migration away from the inpatient setting due to CMS' crack-down on hospital-acquired infections.

Take comparative effectiveness (health economic) study of your technology more seriously. This information bolsters the need for certain health economic messaging, whether as part of a larger prospective study or upon retrospective review of procedures performed. For those procedures which may avoid requiring the use of central lines to the blood stream, or which otherwise may be shown to reduce the incidence of infection, the use of novel, alternate procedures can steer facilities clear of this issue, when comparing like inpatient procedures to one another.

Update study protocols to allow for prospective data collection on the issue of infection type(s). If your organization intends... **Read More**

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Distributor Relationships – Compliance Best Practices & Items to Consider

Mar.2.2012

by Christopher Gingras, FACHE CFE FHFMA

The vast majority of medical device companies utilize independent distributors to sell and market their products to healthcare professionals. When distributors are in the field, they are representing the organization whose products they are marketing. If your distributors act in an unprofessional or illegal manner it exposes your company to compliance risks and almost as importantly, harms the marketplace reputation that you have worked so hard to build. To protect your organization's reputation and reduce compliance risk it is imperative that independent distributors are held to the same high standards expected of employees.

In defining your distributor relationships and drafting contractual agreements, consideration should be given to the following points:

- A copy of your Code of Conduct or a summary should be provided to the distributor for further distribution to all of their employees. Language should exist in the contract stating that the distributor has received and agrees to comply with the organization's code of conduct. This could be accomplished by referring them to your organization's website where a copy of the Code of Conduct can be found.
- Information should be provided on the compliance hotline and its usage. This is most likely covered in the Code of Conduct however it is important that distributors are aware of the anonymous compliance reporting hotline available to them so they can report any compliance issues or questions.

Read More

When to Submit a 510(k) versus the Custom Device Designations for a Change to an Existing Device

Feb.17.2012

by Erela Dana

As each company develops and modifies their devices, the question will ultimately come up at some point of whether a change or line expansion to an already marketed device needs a 510(k). The FDA no longer teaches the catch all route of "letter to file", instead they take a very conservative approach when understanding the need for a 510(k). Some companies have attempted to attach the word "custom" to the size additions because these are not for the normal patients, but for the very small or very large patients. The FDA however sees the custom regulation differently.

So how does one decide whether a modification to a device needs a 510(k) or whether it truly falls under the custom device designation?

Any modification to a previously cleared device that could significantly impact the safety and effectiveness which is defined as the threshold under 21 CFR 807.81(a)(3), will require a new 510(k) submission. This statement could be interpreted a number of different ways. For instance, if you are adding a larger size to your device line, does this significantly impact the safety and effectiveness of the device? Probably not, but what if that size causes more wear due to its larger size, what if the attachment, range of motion, or mechanics are different than that in the cleared 510(k)? An available FDA draft guidance document entitled "**510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device**" issued on July 27, 2011 helps medical device companies determine whether a 510(k) is necessary when a change is made to an existing device. **Read More**

AHRQ Solicits Comments on Lumbar Fusion for DDD by Feb 21

Jan.31.2012

by Jeffrey D. Zigler, J.D. and Timothy Hunter

The Agency for Healthcare Research and Quality (AHRQ) recently posted a notice that it will be soliciting comments until February 21, on the issue of Spinal Fusion for Painful Lumbar Degenerative Disc or Joint Disease. AHRQ wants to understand whether the use of spinal fusion in the treatment of adults with low back pain caused by degenerative disc disease (DDD), lumbar stenosis, or degenerative spondylolisthesis

- offers acceptable peri-operative outcomes (i.e., surgery time, blood loss, length of stay);
- has a sustainable impact on patients' function, quality of life, or pain reduction; and
- affords patients clinical benefits that outweigh the potential adverse events associated with its use

Following completion of the comment period, AHRQ may elect to pursue development of a formal technology assessment or other review document that can be used by CMS or other health insurance payors to inform coverage determinations. Given AHRQ's description of the evidence, including conclusions drawn from the 2006 Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), it appears that any analysis performed will pre-suppose that limited published evidence exists to demonstrate the safety and clinical efficacy of spinal fusion in the lumbar spine. **Read More**

5 Tips to Help Your Clinical Study Site Prepare for an FDA Audit

Jan.27.2011

by Abigail Allen

In order to avoid a 483 and possibly an FDA warning letter, you must be prepared for a site inspection from FDA. Following the 5 essential tips below will help you and your site prepare for, and successfully pass, an FDA audit:

1. **Assume you WILL be audited**. By keeping this mindset, whether you receive a call from the FDA or not, you will have better prepared yourself and your staff for your FDA filing at the end of the study. In 2010, the FDA's bioresearch monitoring programs inspected 400 Clinical Investigator's.
2. **Always Be Prepared**. You and your staff should know exactly what to do from the moment the auditor calls to schedule the audit, to the moment he/she leaves the close-out visit. I have included a few reminders below:
   - Have a plan relating to how the person who answers the phone should handle the call. He/She should know your availability, ask what study the auditor is inspecting, and find a mutually convenient time to schedule the meeting. Regardless of when the auditors come, you must allow them access to your site and files.
   - When the Inspector walks in the door, verify credentials and make sure he/she completes a Notice of Inspection (FDA Form 482) for you and your staff.
   - Have a point person in the office who will stay with the auditor at all times. This person will be responsible for everything the auditor reviews. Remember to keep a copy of everything he/she copies for themselves.
   - Respond to all requests as quickly as possible. This is easier to do if you are very familiar with your regulatory binders... **Read More**

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Regulatory Challenges in Getting Total Disc Replacements onto the Market in an Era of Increased FDA Scrutiny

Jan.25.2012

by Kevin McGowan, Ph.D.

Glenn Stiegman and I recently authored an article for the journal Seminars in Spinal Surgery entitled, "Regulatory Challenges in Getting Total Disc Replacements onto the Market in an Era of Increased FDA Scrutiny." The complete article is in press and can be found at the journal's website.

Since the first total disc replacement (TDR) was approved in 2004, there have been a total of five TDR's approved by the FDA. However, data from a June 2006 marketing report[i] indicated 26 clinical studies of TDR's underway (excluding those approved PMA devices) and, in the 5+ years that have passed since that publication, there have been zero (0/26) PMA approvals or FDA panel meetings related to any of these products. While companies may be facing obstacles such as manufacturing prior to FDA approval, one can reasonably postulate the clinical study designs and execution are interfering with successful clinical study completion, PMA submission, and PMA approval. **Read More**

Government Scrutiny of Off Label Promotion Continues to Increase for the Medical Device Industry

Jan.13.2012

by Christopher Gingras, FACHE CFE FHFMA

As evidenced by recent settlements and numerous investigations of medical device companies, including the recent Johnson & Johnson Risperdal settlement of over $1,000,000,000, the government is VERY interested in off label promotion.

While in general it is permissible for a product to be used off label when clinically appropriate it is NEVER appropriate for a medical device company to promote off label use of a product. In the interest of patient safety the government does allow a medical device company to provide scientific off label information to a clinician if the request is UNSOLICITED and the information provided needs to meet very specific criteria as outlined in FDA guidance.

The key point to keep in mind is that the request needs to be unsolicited. A sales representative cannot hand out business cards with the heading "call for off label information" for example...**Read More**

MCRA's Orthopedic Intelligence Webinar Series

The Future for Spine Reimbursement

Date & Time of Webinar:
Wednesday, May 9, 2012
1:00 PM EST

CLICK HERE TO REGISTER

For more information on MCRA's Upcoming Webinars please visit www.orthopedicintelligence.com/webinars/

Top Orthopedic Roundup Today News Articles during Q1, 2012

Clinical, Regulatory, IP, Compliance, Reimbursement

1. Crosstrees Medical, Inc. Completes Enrollment of USA IDE Study for Percutaneous Vertebral Augmentation (PVA) (Mar)
2. Benvenue Medical Starts Enrolling Patients in the Post-Market LIFT Study on the Luna Interbody Spacer System for Degenerative Disc Disease (Mar)
3. Simpirica Spine Receives Approval to Begin U.S. IDE Pivotal Study of Its LimiFlex™ Spinal Stabilization System (Mar)
4. FDA to discuss risks and benefits of metal-on-metal hip replacements (Mar)
5. Cigna puts medical procedure prices online (Mar)
6. FDA and industry reach agreement in principle on medical device user fees (Feb)
7. Orthopedic device CEO fined for distributing products without FDA's OK (Feb)
8. Zimmer and ISTO Technologies Announce Phase III Clinical Study to Evaluate the Effectiveness of Engineered Juvenile Cartilage to Repair Damaged Knees (Feb)
9. Stem Cells and the Lawsuit That May Shape Our Medical Future (Feb)
10. SI-BONE Awarded Significant "Across Bones" Patent Allowance (Feb)
11. Hip Fractures: Coexisting Medical Conditions Increase Treatment Costs and Lengthen Hospitalization, Study Finds (Jan)
12. FDA Issues Guidance for Industry Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage (Jan)
13. Accentus Medical anti-infective Agluna® technology awarded CE mark as component of Stanmore Implants METS tumour replacement system (Jan)
14. Interventional Spine, Inc. Announces FDA Clearance of its Opticage™ Expandable Interbody for Treatment of Degenerative Disc Disease (Jan)
15. Stryker Reaches Settlement with the U.S. Attorney's Office (Jan)

Finance, M&A & Other Corporate Transactions

1. Bacterin Announces Record 2011 Revenue of $30.1 Million; Up 96% Year-over-Year (Mar)
2. Emerge Medical Awarded an Orthopedic Trauma Agreement with the Premier Healthcare Alliance (Mar)
3. NLT SPINE Secures Additional Funding To Fuel Its Platform Development For Minimally Invasive Spine Procedures (Mar)
4. Bioscience Authority awards $3.3 million in grants (Mar)
5. KUROS and SYNTHES, INC. Announce License and Development Agreement (Mar)
6. Banner Announces Long-Term Exclusive Contract to Stock and Market Cannulated Bar Manufactured by Veridiam, Inc (Mar)
7. Amedica Corporation Completes $30 MM Financing to Expand Market Share of Proprietary Silicon Nitride Ceramic (Feb)
8. Osseon® Announces International Distribution Agreement with Aesculap (Feb)
9. SBi Founder and CEO Sees Continuing Growth in Small Bone and Joint Sector of Orthopedics Market (Feb)
10. J.&J. Offers Concessions to Win Approval for Synthes Deal (Feb)

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11. BioRestorative Therapies Signs License Agreement for Stem Cell Disc/ Spine Procedure (Jan)
12. Simbionix acquires arthroscopic surgery simulation technology (Jan)
13. Active Implants Corporation Receives $10 MM in Convertible Debt to Focus on Clinical Study (Jan)
14. Zimmer Announces Acquisition of Synvasive Technology, Inc. (Jan)
15. Thermogenesis Signs Worldwide Res-Q System Distribution Agreement With Arthrex for Sports Medicine Applications (Jan)

Technology, Product & Industry

1. Amedica Announces Launch of New Facet Joint Implant (Mar)
2. Metal-on-metal hip implants: No reason to take risk, study warns (Mar)
3. Benvenue Medical Announces U.S. Launch of the Blazer™ Vertebral Augmentation System (Mar)
4. New method doubles storage time for cartilage transplant tissue (Mar)
5. Interventional Spine, Inc. to Present the PerX360 System(TM) at the ISASS Annual Meeting in Barcelona, Spain (Mar)
6. Tibial Fractures - STORM from Intelligent Orthopaedics Shown to Reduce Radiation Exposure During Surgery (Mar)
7. BioMimetic Therapeutics, Inc. to Introduce Augmatrix™ Biocomposite Bone Graft Product Line at AAOS (Feb)
8. DJO Global Showcases New Bracing and Supports Products at American Academy of Orthopedic Surgeons Meeting (Feb)
9. POLARCUP™ Dual Mobility Hip System From Smith & Nephew Now Available in US (Feb)
10. The CORE Institute Offers New Procedure to Save Aching Backs Without Losing a Disc (Feb)
11. CoLS® PEEK Fixation Screws Receives FDA Clearance (Feb)
12. MedShape, Inc. Announces Full Commercial Release of ExoShape® Soft Tissue Fastener (Jan)
13. New Technology to Track Movement and Durability of Implants in Hip and Knee Replacement Patients (Jan)
14. Ellipse Technologies Announces First US Implantation of the PRECICETM Remote-Control Limb Lengthening Device (Jan)
15. Pioneer® Surgical Announces First Human Use of nanOss® Bioactive 3D (Jan)

Operational, HR & Other

1. Arthrex ready to build $25 million Ave Maria plant, create hundreds of jobs (Mar)
2. Utah's Biomerics completes plant upgrade (Mar)
3. Iotron Industries expands with high-tech sterilizing plant in Indiana (Mar)
4. The Molecular Mechanism Responsible For Vertebral Column Degeneration Discovered (Mar)
5. Paradigm Spine, LLC Announces Strategic Promotions and Hiring of Key Personnel to Ensure Long-Term Growth and Success (Mar)
6. Fifty per cent of Enztec staff get the boot (Mar)
7. Zimmer in Warsaw moving part of operation to Memphis (Mar)
8. Michael P. Simpson Joins Small Bone Innovations as President and CEO (Feb)
9. MCRA Hires Former Commercial Insurance Medical Director to Guide Firm's Reimbursement Strategies (Feb)
10. TranS1 Inc. Opens New Training Facility in Raleigh, NC (Feb)
11. Stephen P. MacMillan Resigns as Chairman, President and CEO of Stryker Corporation (Feb)
12. Smith & Nephew to cut 800 jobs worldwide (Feb)
13. Johnson Takes $3 Billion Hit on Hip Recall (Jan)
14. BioMimetic cuts 25% of workforce amid FDA delay (Jan)
15. Feds open up case against Stryker Biotech (Jan)

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

Q1-2012 Orthopedic Panel 510(k) Clearances

Joint

Device Name	Applicant	510(k) #	Decision Date
zimmer persona knee system40	zimmer inc.	K113369	3/27/12
synthes variable angle lcp elbow system268	synthes usa	K120070	3/21/12
pipeline cr primary knee system216	pipeline orthopedics	K113122	3/20/12
metha hip system174	aesculap implant systems, llc	K112682	3/19/12
novation element femoral stem, 12/14 col188	exactech, inc.	K113320	3/16/12
highly cross linked ve central peg patel134	encore medical, l.p.	K113756	3/14/12
adaptive wedge	adaptive specialty, llc	K110662	3/12/12
pipeline total hip system218	pipeline orthopedics	K112802	3/9/12
ascend shoulder system	tornier, inc.	K113413	3/9/12
arthrex universii xl glenoid-pegged, art	arthrex, inc.	K120044	3/8/12
restoris partial knee application (pka),232	mako surgical corporation	K112507	3/1/12
apex revision knee systems	omni life science, inc.	K112891	2/29/12
dynanail ankle arthrodesis nail108	medshape, inc	K113828	2/29/12
vanguard complete knee system274	biomet manufacturing corp.	K113550	2/29/12
journey ii deep dished articular inserts144	smith & nephew, inc.	K113482	2/27/12
linear hip stem, size 5164	encore medical, l.p.	K120241	2/24/12
smr modular glenoid-metal-back smr modul250	limacorporate s.p.a.	K113254	2/24/12
kneetec pfj&hls kneetec patellar compone150	tornier	K111970	2/23/12
wagner cone prosthesis system278	zimmer gmbh	K113556	2/17/12
comprehensive reverse shoulder-mini base	biomet, inc.	K120121	2/16/12
eaum total knee system110	corentec co., ltd	K110404	2/16/12

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Joint

Device Name	Applicant	510(k) #	Decision Date
conformis itotal cruciate retaining (cr)	conformis, inc.	K113378	2/15/12
metatarsal decompression implant surgica172	solana surgical llc	K113752	2/6/12
conformis itotal cr knee replacement system	conformis, inc.	K120068	2/3/12
conserve thin shell	wright medical technology, inc.	K113322	2/3/12
klassic knee system148	total joint orthopedics, inc.	K112906	2/1/12
gmk resufacing patella size 4128	medacta international	K113571	1/27/12
comprehensive reverse shoulder humeral t	biomet manufacturing corp.	K113069	1/11/12
aptus wrist arthrodesis plates	medartis ag	K112169	1/6/12
zimmer patient specific instruments plan282	materialise n.v.	K112301	1/6/12
apex arc hip stem	omnilife science inc.	K113242	1/5/12
promos modular shoulder system226	smith & nephew, inc.	K113012	1/5/12
smith & nephew inc. unicompartmental and248	smith & nephew, inc.	K113038	1/5/12
novation integrip acetabular augments, g190	exactech, inc.	K113609	1/4/12

Spine

Device Name	Applicant	510(k) #	Decision Date
zavation ibf system32	zavation llc	K120576	3/28/12
rexious hook fixation systems30	dio medical co., ltd.	K113324	3/28/12
independence spacer38	globe medical, inc.	K120101	3/27/12
venus spinal fixation system42	l&k biomed co., ltd	K120270	3/26/12
palls m spinal system44	korea bone bank co., ltd	K120538	3/23/12
solitarie peek anterior spinal system-to252	biomet spine & bone healing technologies	K120557	3/19/12
chesapeake spinal system	k2m, inc.	K120031	3/16/12
foundation spinal system122	the skeletal design partnership ltd.	K120074	3/14/12
synster cervical cage, alif cage, plif c264	bm korea co., ltd.	K111820	3/14/12
aileron interspinous fixation system	life spine	K113157	3/13/12
asfora bullet cage	medical designs, llc	K112648	3/13/12
nuvasive coroent no-profile system192	nuvasive, inc.	K112561	3/13/12

Spine

Device Name	Applicant	510(k) #	Decision Date
pioneer posterior cervico thoracic syste212	pioneer surgical technology, inc.	K112757	3/12/12
reliance lumbar ibf system228	reliance medical systems, llc	K113540	3/12/12
lanx spinal fixation system156	lanx, llc	K120399	3/9/12
power adaptor instrument accessory224	stryker corp.	K120434	3/8/12
leucadia 4.5 mm pedicle screw system158	phygen, llc	K120355	3/7/12
mobis, moval, semial, tetrismodel peek a176	signus medizintechnik gmbh	K111792	3/5/12
plif cage220	eisertech, llc	K113478	3/5/12
spineology peek lumbar interbody fusion 256	spineology, inc.	K120293	2/29/12
mectalif transforaminal168	medacta international, sa	K120024	2/28/12
neon system184	ulrich gmbh & co. kg	K113346	2/28/12
sintea plustek anterior cervical plate s244	sintea plustek, llc	K112861	2/24/12
acu-cut vertebral augmentation system	ascendx spine, inc.	K113452	2/17/12
arena-c cervical intervertebral body fus	spinefrontier, inc.	K113518	2/16/12
eclipse vertebral spacer system-cervical112	apollo spine	K120143	2/16/12
icon (tm) modular pedicle screw system138	orthofix, inc.	K111448	2/16/12
focus spinal system118	l&k biomed co., ltd	K120140	2/15/12
coflex-f	paradigm spine, llc	K112595	2/13/12
spinevu endoscopic spine system (sess)258	spine view, inc.	K113362	2/10/12
cd horizon voyager spinal system	medtronic sofamor danek	K113529	2/9/12
depuy pulse thoracolumbar screw system100	medos international sarl	K113396	2/8/12
pathway avid206	custom spine, inc.	K111726	2/6/12
perimeter interbody fusion device210	medtronic sofamor danek usa	K113642	2/6/12
coral spinal system	theken spine, llc	K120047	2/3/12
pass lp spinal204	medicrea international	K112736	2/1/12
savannah technologies spinal system240	savannah technologies llc	K113755	2/1/12
synthes uss connectors266	synthes spine	K113149	2/1/12
santorini spinal system238	k2m, inc.	K111294	1/27/12
giza(r) vertebral body replacement126	eden spine, llc	K112429	1/26/12
pioneer release laminoplasty plating sys214	pioneer surgical technology, inc	K113218	1/26/12

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Spine

Device Name	Applicant	510(k) #	Decision Date
rise spacer234	global medical, inc.	K113447	1/26/12
spineology peek bullet lumbar interbody 254	spineology, inc.	K113030	1/26/12
cardiff anterior cervical plate system	seaspine, inc.	K112206	1/25/12
xenon(tm) pedicle screw system280	alphatec spine, inc.	K111634	1/25/12
ivas balloon catheter142	stryker corporation	K113154	1/24/12
lexus anterior cervical plate system162	l&k biomed co., ltd	K113509	1/20/12
opticage interbody fusion device198	interventional spine, inc.	K113527	1/20/12
reliance spinal screw system230	reliance medical systems, llc	K110896	1/20/12
nanovis spinal system180	nanovis, llc	K113173	1/19/12
oasys spinal system194	stryker spine	K111719	1/19/12
k2m, pyrenees cervical plate system146	k2m, inc.	K113329	1/17/12
leucadia autolok pedicle screw system160	phygen, llc	K113366	1/17/12
peek prevail cervical interbody device208	medtronic sofamor danek	K113252	1/17/12
caspian	k2m, inc.	K113654	1/12/12
aleutian system	k2m, inc.	K113138	1/10/12
dss stabilization system104	paradigm spine, llc	K113625	1/10/12
ivas 20mm (10 gauge) balloon catheter140	stryker instruments, instruments div.	K113477	1/6/12
focus mis system116	l & k biomed co., ltd	K112643	1/4/12

Trauma

Device Name	Applicant	510(k) #	Decision Date
ellipse precice trauma nail system34	ellipse technologies, inc.	K113695	3/28/12
multifix p knotless fixation device36	arthrocare corporation	K120096	3/27/12
apaceram bone graft substitute46	hoya corporation	K120602	3/23/12
small and large fragments osteosynthesis48	neoortho produtos ortopedicos s/a	K113733	3/23/12
biobolt	arthrex, inc.	K120540	3/20/12
newdeal interphalangeal implant186	newdeal sas	K103623	3/20/12
b-genin, r-genin	berkeley advanced biomaterials, inc.	K113791	3/15/12
citieffe titanium nailing system	citieffe	K113387	3/15/12
aequalis shoulder fracture system, aequa	tornier	K112144	3/13/12

Trauma

Device Name	Applicant	510(k) #	Decision Date
enhatch orthopaedics patient/technique-s114	enhatch orthopaedics llc	K112663	3/12/12
trauma internal fixation systems270	depuy orthopaedics, inc.	K111663	3/12/12
footprint ultra pk suture anchor120	smith & nephew, inc.	K113274	3/6/12
knotilus anchor system152	t.a.g. medical products corporation, ltd	K113297	3/2/12
2.7mm lcp ulna osteotomy system	synthes (usa) products llc	K113364	2/29/12
healix advance br anchor130	depuy mitek inc., johnson and johnson co	K120078	2/29/12
acute innovations biobridge resorbable	acute innovations llc	K120163	2/17/12
arthrex knotless suturetak anchor	arthrex, inc.	K120155	2/17/12
s2 femoral a/r nail s2 femoral comressio236	howmedica osteonics corp.	K113409	2/15/12
polyfuse - neurobone222	atpac medical llc	K111018	2/14/12
set screw for ti trochanteric fixation n242	synthes usa	K120083	2/8/12
callos promodel bone void filler, skaffold MP bone void filler	skeletal kinetics, llc	K112383	2/7/12
ortho solutions extremity fixation impla200	ortho solutions limited	K111678	2/7/12
checkmate metatarso-phalangeal (mtp) arthrodesis system	arthrosurface, inc.	K113762	2/6/12
claw ii polyaxial compression system and Ortholoc 3DSI Locking Screws	wright medical technology, inc.	K113014	1/31/12
twinfix ultra ti, twinfix ultra pk, twin272	smith & nephew, inc.	K112526	1/31/12
maxlock extreme system166	orthohelix surgical designs, inc.	K113048	1/30/12
ncb straight narrow shaft plates182	zimmer gmbh	K113718	1/27/12
gap endo-exo medullary system124	pega medical inc.	K111232	1/26/12
hoffmann 3 modular external fixation sys136	stryker corp.	K111786	1/26/12
mtf new bone voild filler178	musculoskeletal transplant foundation	K113167	1/24/12
synde-lock syndesmosis repair kit262	tarsus medical inc.	K111971	1/23/12
smith & nephew healicoil pk suture ancho246	smith & nephew, inc.	K113294	1/20/12

April 2012

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Trauma			
Device Name	**Applicant**	**510(k) #**	**Decision Date**
cuffink98	cayenne medical, inc.	K112814	1/17/12
parcus 35 knotless peek cf push-in sutur202	parcus medical, llc	K113730	1/17/12
medical facets corical screws, medical f170	medical facets	K112727	1/13/12
various276	depuy mitek, a johnson & johnson company	K112417	1/13/12
acute innovations modular ribloc system	acute innovations llc	K113318	1/12/12
oic cannulated screw system, oic sliding196	the orthopaedic implant company	K113123	1/12/12
suspension clavicle fracture repair syst260	suspension orthopaedic solutions, llc	K113405	1/11/12
labralink suture anchor with inserter, 2154	cayenne medical, inc.	K112960	1/9/12
dne external fixation system102	d.n.e., llc	K113106	1/4/12
dyna locking cannulated screw106	u&i corp.	K112240	1/4/12

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

Q1 2012 - Orthopedic Advisory Premarket Approval (PMA)

Joint			
Device Name	**Applicant**	**PMA #**	**Decision Date**
LCS Total Knee System	depuy orthopaedics,	P830055 S124	3/16/12
Depuy Duraloc Option Cera	depuy orthopaedics,	P040023 S018	3/8/12
LCS Ttotal Knee System	depuy orthopaedics,	P830055 S125	2/21/12
Transcend Hip Articulation	ceramtec ag	P010001 S010	2/14/12
Trilogy AB Acetabular System	zimmer, inc.	P040048 S016	2/10/12
Nexgen LPS-Flex/LPS-Mobil	zimmer, inc.	P060037 S016	2/10/12
LCS Total Knee System	depuy orthopaedics,	P830055 S121	2/9/12
LCS Total Knee System	depuy orthopaedics,	P830055 S122	2/6/12

Joint			
Device Name	**Applicant**	**PMA #**	**Decision Date**
Oxford Partial Knee System	biomet, inc.	P010014 S033	2/3/12
Euflexxa (1% Sodium Hyalu	ferring pharmaceutic	P010029 S013	1/27/12
Reflection Ceramic Hip System	smith & nephew, inc.	P030022 S020	1/20/12
Trident Systems	howmedica osteonics	P000013 S010	1/18/12
LCS Total Knee System	depuy orthopaedics,	P830055 S119	1/6/12
Synvisc & Synvisc-One	genzyme corporation	P940015 S024	1/5/12

Spine			
Device Name	**Applicant**	**PMA #**	**Decision Date**
Infuse Bone Graft	medtronic sofamor da	P000054 S029	3/15/12
Infuse Bone Graft/LT-Cage	medtronic sofamor da	P000058 S042	3/15/12
Bryan Cervical Disc	medtronic sofamor da	P060023 S001	3/9/12

Trauma			
Device Name	**Applicant**	**PMA #**	**Decision Date**
EBI Osteogen Implantable	biomet spine & bone	P790005 S048	1/20/12

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.