

Pipeline

Latest Premarket Approvals

Device	Company	Date
Neurostimulation Systems for Spinal Cord Stimulation	Medtronic Inc.	4/30/2014
EON Mini IPG Neurostimulation System	St. Jude Medical	4/25/2014
EON CTM IPG Neurostimulation System	St. Jude Medical	4/25/2014
SCS Implantable Neurostimulator System Families	Medtronic Inc.	4/24/2014
Precision and Precision Spectra Spinal Cord Stimulator Systems	Boston Scientific Corp.	4/21/2014
Precision Spectra Spinal Cord Stimulator System	Boston Scientific Corp.	4/17/2014
Biomet Orthopak Non-Invasive Bone Growth Stimulator System and Biomet Spinalpak Non-Invasive Spine Fusion Stimulator	EBI L.P.	3/26/2014
Restoreprime Neurostimulator, Primeadvanced Neurostimulator, Irel 4 Neurostimulator, Primeadvanced SureScan MRI Neurostimulator	Medtronic Inc.	3/19/2014
Medtronic Spinal Cord Stimulation Systems	Medtronic Inc.	3/13/2014

For a complete list, visit <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm>.

Latest 510(k) Approvals

Device	Company	Date
Integra Expandable Intervertebral Body Fusion Device System	Seaspine Inc.	5/1/2014
Xcage Interbody Fusion System	Ouroboros Medical	5/1/2014
General Spinal System	Tianjin Walkman Biomaterial Co.	4/29/2014
Anatomic PEEK PTC Cervical Fusion System	Medtronic Sofamor Danek USA Inc.	4/28/2014
Octane Elevate Spinal Implant System	Exactech Inc.	4/25/2014
Reliance Anterior Cervical Plate	Reliance Medical Systems LLC	4/25/2014
Polaris Spinal System Translation Screw	EBI LLC	4/24/2014
Fortress Pedicle Screw System	Spineology Inc.	4/23/2014
Anyplus PEEK Cages	GS Medical Co.	4/18/2014
ZIP MIS Interspinous Fusion System	Aurora Spine Inc	4/17/2014
Inter V Kyphoplasty Catheter	Pan Medical LTD	4/16/2014
Intess Cervical Cage System	Kalitec Direct	4/16/2014
Cogent Med-ILF	Cogent Spine LLC	4/15/2014
Cervical Stand Alone System	Orthofix Inc.	4/14/2014
Picasso II MIS Spinal System	Accel Spine	4/14/2014
Proposed Optimus	Custom Spine Inc.	4/11/2014
Spineworks Anterior Lumbar Device	Spineworks LLC	4/11/2014
Orthos Posterior Stabilization System	Camber Spine	4/8/2014
Medinaut Kyphoplasty System	Imedicon	4/7/2014

For a complete list, visit www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm.

Recruiting Clinical Trials

Sponsor	Trial name	Identifier	Purpose
Rush University Medical Center	Multimodal Analgesia Versus Routine Care Pain Management	NCT01861743	The study will determine if postoperative pain and rate of recovery are improved for patients who undergo spine surgery using multimodal analgesia compared to usual analgesic care.
Indiana University	Incidence of Venous Thromboembolism in Children Undergoing Elective Neurosurgical Procedures	NCT02037607	The study will determine the frequency at which children undergoing elective neurosurgical procedures develop blood clots in the deep veins of the legs during hospitalization.
Greenwich Hospital	Neurosurgery Patient Outcomes in Treating Spinal Disorders	NCT01220921	The study will create a multicenter cooperative research group encompassing academic and community-based spinal practices.

For a complete list, visit www.clinicaltrials.gov

Sources: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm; www.clinicaltrials.gov.

Zimmer to combine with Biomet

Zimmer Holdings Inc. and the parent company of Biomet Inc. recently announced that the boards of directors for both companies have approved a definitive agreement for Zimmer to purchase Biomet in a cash and stock transaction. Valued at approximately \$13.35 billion, the transaction, which will include the assumption of net debt and is subject to both customary closing conditions and regulatory approvals, is expected to be finalized in the first quarter of 2015.

The combined company will continue to be headquartered in Warsaw, Ind., and is expected to deliver a more comprehensive portfolio of solutions with enhanced cross-selling opportunities and additional benefits to both health care

“This combination is certainly about growth. Together the combined company will be more competitive in our core knee and hip franchises, with a more diverse revenue base through increased scale and faster growing markets in adjacent categories. We will also gain meaningful entry into sports medicine, and we will have a research and development team that will power enhanced innovation,” Dvorak said in the conference call.

Dvorak also said the company is anticipating approximately \$270 million in synergies by 2017, with approximately \$135 million in the first year.

In the press release, **Jeffrey R. Binder**, Biomet’s president and chief executive officer, stated, “The combination with Zimmer will prepare us to compete as a stronger entity in the medical device industry of the future. Our combined scale will extend the reach and influence with which we pursue our common passion: delivering products and services that benefit our customers and the patients we ultimately serve. Biomet and Zimmer are blessed with talented team members and independent sales people who are dedicated to their companies and to their customers. With today’s announcement we are now additionally committed to blending and maximizing the best of our combined talents, capabilities, technologies and cultures to bring to life a great new company.” ■

www.zimmer.com/en-US/hcp/news/news-biomet-04-24-2014.jsp.

PERSPECTIVE

Mergers and acquisitions appear to be the order of the day in our present health care environment. The announced sale of Biomet Inc. to Zimmer



David A. Wong

Holdings Inc. is only the latest example of the frenzy which has dominated the orthopedic/spine device industry in recent years. Surgeons, but especially our patients, can only hope that the result of such transactions includes a continued reliable supply of diverse, reasonably priced implants, as well as a commitment to orthopedic and spinal research, innovation and education.

— **David A. Wong, MD, MSc, FRCS(C)**

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Disclosure: Wong is employed part-time as director, Advanced Center for Spinal Microsurgery at Presbyterian St. Luke’s Medical Center, in Denver,

which uses Zimmer and Biomet products.

“This combination is certainly about growth. Together the combined company will be more competitive in our core knee and hip franchises.”

— DAVID DVORAK

stakeholders and stockholders. Following the transaction’s completion, **David Dvorak**, president and chief executive officer of Zimmer, will become president and chief executive officer of the combined company. Two representatives of Biomet’s principal stockholders will join the combined company’s board, which will be expanded accordingly.

“This milestone combination creates a leading innovator in the musculoskeletal industry that we believe will deliver significant benefits to patients, providers, and all of our health care stakeholders. Together we will be better positioned to shape solutions for the evolving health care industry,” Dvorak said in a conference call the morning of the announcement.

Zimmer will pay \$10.35 billion in cash and will issue Biomet’s equity holders aggregate shares of Zimmer common stock valued at \$3 billion. The cash portion will be funded by existing cash on hand as well as proceeds obtained from a newly committed \$3 billion senior unsecured term loan and newly issued senior notes. Zimmer expects to refinance certain of its debt as part of the transaction, including its existing \$250 million notes due 2014 and bank debt outstanding, as well as certain Biomet debt.

The combined company expects to maintain Zimmer’s investment grade credit ratings. Upon closing of the transaction, Zimmer stockholders are expected to own approximately 84% of the combined company, and Biomet shareholders are expected to own approximately 16%.