

Editorial

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Orthopedic Innovation?

Many in the orthopedic industry will proudly point to the vast improvements in orthopedic technology available to patients. These include new bearing surfaces, navigation, new implant designs and materials, among other initiatives. These innovations are brought out under the oversight of the FDA, which has the responsibility to assure the “safety, efficacy, and security of drugs, biologics, medical devices, food, and cosmetics.” The division of the FDA responsible for orthopedic implants and other implantable devices is the Center for Devices and Radiological Health (CDRH). Before medical devices can be sold in the United States, they have to go through an FDA review process, either the PMA (Pre-market approval) for devices that are fairly new, or the 510-K review which is designed for devices that are similar to those currently on the market. A PMA must be submitted with clinical data demonstrating the safety and efficacy of the device. A 510-K will typically refer to “predicate devices” that have been previously approved by the FDA (see Smith & Nephew 510-K above.)

All of the data regarding PMAs and 510-Ks is readily available on the web (www.fda.gov). The total number of PMAs for orthopedic products submitted since 1976 is about 33—since 2002, 21 original PMAs have been submitted. Of these recent

FDA's 510Ks, PMAs for device approvals

510K: “Requires device manufacturers to notify FDA of intent to market a medical device...allows FDA to determine whether the device is equivalent to a device already on market (“substantial equivalence”)

- No clinical data required for approval (usually)
- User fee \$3,404 in FY 2008 ¹
- 3,130 submitted in FY 2005
- Review time about 49 days in FY 2005

PMA (Pre-market approval): “FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.”

- “Supplemental” PMAs to change material, components, design, color, labeling in middle of PMA
- Requires clinical data submission for evaluation
- User fee of \$185,000 for FY 2008 ¹
- 43 submitted in FY 2005
- Review time 271 days in FY2004 for original and supplements

¹Discounts/waivers for small business and pediatric applications

Source: www.fda.gov

Sample 510-K

K071790 August 17, 2007

Smith & Nephew Gender Knee Systems

“The Smith & Nephew, Inc. Gender Knee Systems are the existing Smith & Nephew, Inc. Genesis II, Legion, and Journey BCS Knee Systems. This premarket notification seeks only to add gender-related claims for these existing total knee systems previously cleared by FDA marketed by Smith & Nephew. No new total knee components [are] being introduced as a result of this premarket notification.”

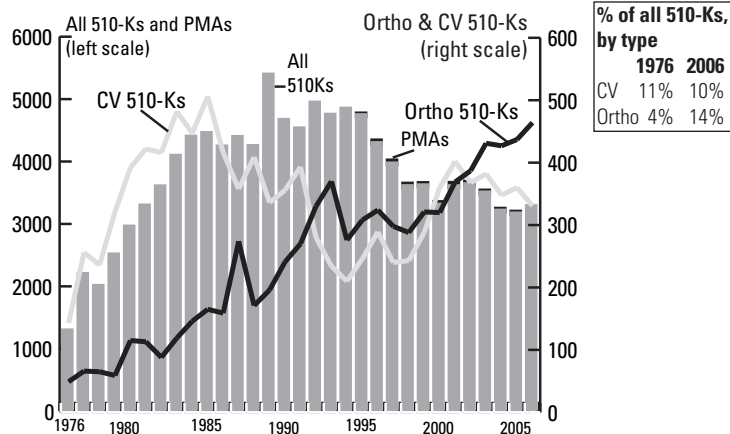
www.fda.gov/cdrh/pdf7/k071790.pdf

Orthopedic related PMAs, 2002-2007

Year	Company	Type	PMA
2007	MSD	Disc	Prestige Cervical Disc
	Exactech	COC	Novation ceramic articular
	Corin USA	Resurface	Cormet hip resurfacing
2006	Zimmer	Knee	NexGen LPS-Flex mobile bearing
	Synthes Spine	Disc	Prodisc-L total disc
	Zimmer	COC	Trilogy AB acetabular
	Stelkast	COC	Surpass Acetabular
2005	S&N	Resurface	Birmingham Hip Resurfacing
	Biomet	COC	C2 A-Taper acetabular
	Kyphon	Spine	X Stop interspinous process
2004	DePuy	COC	Duraloc option ceramic
	S&N	COC	Reflection ceramic acetabular
	DePuy Spine	Disc	Charite artificial disc
2003	Biomet	Uni knee	Oxford meniscal bearing
	Anika	HA	Orthovisc high molecular
	Wright	COC	Ceramic Transcend
2002	Stryker	COC	Osteonics ABC/Trident
	Ascension	Finger	MCP
	Genzyme	HA	Synvisc Hylan G-F
	SBI	Wrist	Braun-Cutter trapez-metacarpal
	MSD	BMP	Infuse Bone graft

Source: www.fda.gov

PMAs, 510-Ks, 1976-2006; Orthopedic and Cardiovascular related 510-Ks and PMAs



Source: www.fda.gov

ones, eight are for ceramic-on-ceramic hip systems, two for femoral resurfacing, two for artificial discs, and the remaining handful for knees, hyaluronic acid, bone morphogenic protein, and orthopedic products.

Other observations about the 510-Ks and PMAs (both ortho and non-ortho):

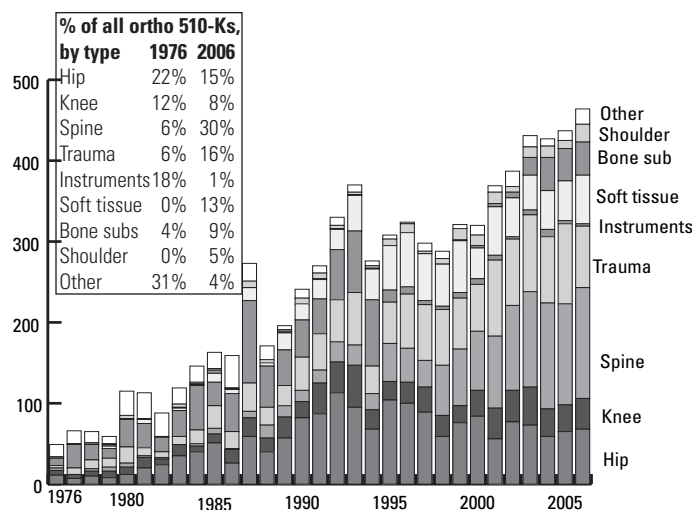
- The number of 510-K's vastly outnumbers the PMAs submitted and approved by the FDA. For example, in 2005, the FDA received 43 original PMAs and 3,130 510-Ks for all 18 medical panels. Medical panels include specialties such as neurological, ophthalmic, radiological, circulatory system, and orthopedics.
- PMAs can be extended over years if not decades. The FDA is supposed to be notified if a device manufacturer has changed manufacturing, materials, design, software, or critical factors in a device. These are communicated to the FDA through a supplement to the original PMA. For example, Biomet's PMA for their Oxford Unicondylar knee has 16 supplements; Depuy's PMA for their LCS mobile bearing knee had 99 supplements dating from 1971 to 2006.
- The number of PMAs and 510-Ks has decreased over the last 10 years. The peak number of PMAs approved was in 2001 with 53, and 510-Ks approved peaked in 1995 with 7,948.
- While the total number of 510-Ks have declined, the number attributable to orthopedics has increased since 1976, especially those related to spinal implants.

One could consider the 510-Ks and PMAs as an index into the amount of innovation taking place. Since these approvals are supposed to precede the marketing of a medical device, one would expect to see more parts available related to these requests.

To test that hypothesis, an analysis of the parts added to the *Orthopedic Network News* database is displayed at right. This database has been maintained since 1992, and contains all of the parts obtained from orthopedic manufacturer price lists during that time. The number of parts added since 1999 has been between 10,000 and 25,000 each year, and has declined over the last four years. In 2007, the largest group of new parts were from spinal implants (8,868); in the entire database, the number of unique part numbers for pedicle screws, used in spinal fusion, numbers over 13,000, or more than three times the number of hip stems (4,304).

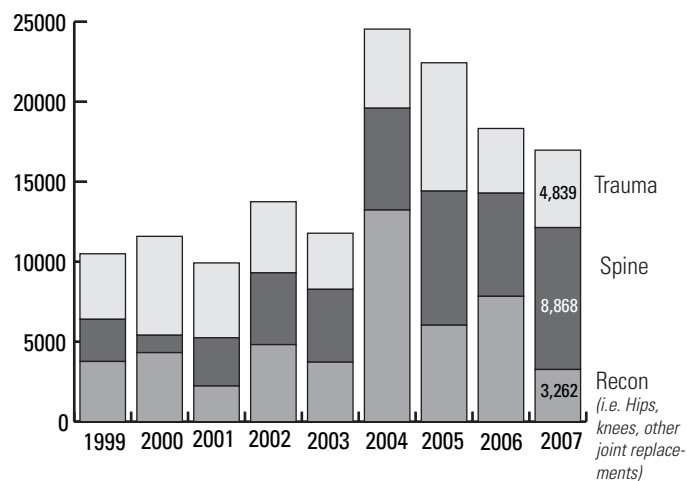
Since one of the reasons manufactures provide for justifying their price increases each year is "technological innovation," it would be helpful to see which products, parts, and FDA submissions they consider as innovative. ■

Orthopedic related 510Ks approved by the FDA, 1976 - 2006



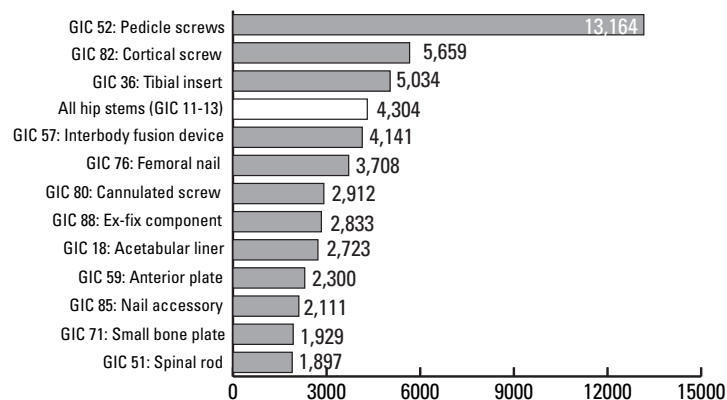
Source: www.fda.gov

New parts in www.OrthopedicNetworkNews.com database, by year added and segment



Source: www.OrthopedicNetworkNews.com. Trauma segment includes maxillofacial parts, excludes instruments and other non-implanted components.

Current part numbers in the Orthopedic Network News database



Source: www.OrthopedicNetworkNews.com. Includes parts added after January 1, 1999 with a current price (2007 or 2008). Excludes parts assigned to GIC 94 (Instruments.)