

KIP A. PETROFF

Board Certified Personal Injury and
Civil Trial Lawyer
Texas Board of Legal Specialization

10440 N. Central Expressway
Suite 1540
Dallas, TX 75231

Telephone: (972) 294-7530
web: KipPetroff.com
kpetroff@petroffassociates.com

May 23, 2018

Re: Chicago “Bet the Company” MDL Seminar + What’s So Special About Smith & Nephew Metal Hip Implant Cases?

Dear Colleagues:

There is a new type of metal on metal hip implant case recently sent to the Smith & Nephew MDL that is among the strongest products liability cases being litigated today. It is a metal on metal hip implant construct involving Smith & Nephew metal parts that were never approved for use together. A similar Smith & Nephew part is likely to be included in this MDL any minute now, thereby making the Smith & Nephew MDL a relatively new MDL as hip implant MDLs go. These new cases highlight some of the factors that can make or break any products liability personal injury case. It is useful to consider this information even if you are not currently defending or prosecuting any Smith & Nephew hip implant cases.

The Smith & Nephew cases described here involve products that couldn’t gain FDA marketing clearance despite multiple attempts and submissions to the FDA over a four-year period. A meeting was held with FDA officials and the company hired outside experts on FDA matters, but the company still failed to convince the FDA. The company sold the devices anyway.

- **HOW TO SPOT A GOOD PRODUCTS LIABILITY CASE.**

All products liability cases involve the age old, three-part question about the company’s knowledge and product-related conduct:

1. *What* did the company know?
2. *When* did they know it?
3. *What* did they do about it?

Seems like every discussion about products liability cases eventually turns to these three questions. I have used this exact trilogy of questions when it helps me at trial, and Zimmer, Inc. used it successfully against me in a hip implant trial last year. Whether you represent Plaintiffs or Defendants, the answers provide a good, common sense framework for assessing the facts and your likely success with any particular products liability case. The Judge, jury, and your opponent have likely already begun framing their own conclusions.

With the above three questions in mind, consider what Smith & Nephew executives at the highest levels of the company knew about their metal on metal hip implants and what they did about it when they learned it.

- **BACKGROUND OF SMITH & NEPHEW HIP IMPLANTS.**

In the past several years, there have been many thousands of product liability lawsuits filed in U.S. courts claiming medical problems from allegedly defective metal on metal hip implants. The following brief history will demonstrate what most of us already know – metal on metal hip implant cases can make for a good trial story. Several MDLs have been established for metal on metal hip implant cases against Zimmer, DePuy, Stryker, Wright Medical, and Biomet. The organization of these MDLs occurred while the FDA was acquiring knowledge and voicing increased concern about the emerging medical problems associated with this class of implantable metal medical device. The FDA began a process in 2011 that resulted in a Final Order on February 18, 2016 that essentially banned metal on metal hip implants from the total hip replacement market in this country. Thousands of cases have settled as part of the MDL process and some have been resolved in other ways, but more than ten thousand metal on metal hip implant cases are still on file in Federal and state courts today. Many thousands of people have suffered significant injuries because of metallosis and other serious health problems directly linked to this dubious class of metal medical device. Revision surgeries involving metal on metal hip implants continue to occur at an alarming rate.

A newcomer to the hip implant MDLs is Smith & Nephew, Inc. The Smith & Nephew MDL wasn't even created until March of last year, and the cases discussed below were only added to MDL 2775 beginning in January of this year. Lawyers with experience in the other hip implant MDLs may find the significant differences between their cases and the Smith & Nephew cases intriguing. A quick review of the products involved in MDL 2775 will make it easier to recognize what makes the Smith & Nephew total hip arthroplasty cases different from the others.

MDL No. 2775 is formally known as the “*Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation, MDL 17-MD-2775.*” It is pending in front of Senior Judge Catherine C. Blake in the U.S. District Court in Baltimore, Maryland. A detailed discussion of the background of the Smith & Nephew MDL can be found in Judge Blake's March 26, 2018 written opinion concerning Smith & Nephew's Motion to Dismiss. *See Memorandum, In re: Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation, CCB-17-2775, Document 608 (D. Md. Mar. 26, 2018).* This MDL Memorandum Order is recommended reading for anyone with Smith & Nephew metal hip cases in the MDL or in state court.

MDL 2775 now involves two types of Smith & Nephew hip implant cases with another one soon to be included. The two new ones involve a combination of metal parts that the FDA never approved or cleared at all¹. This alone makes MDL 2775 unusual, because other hip

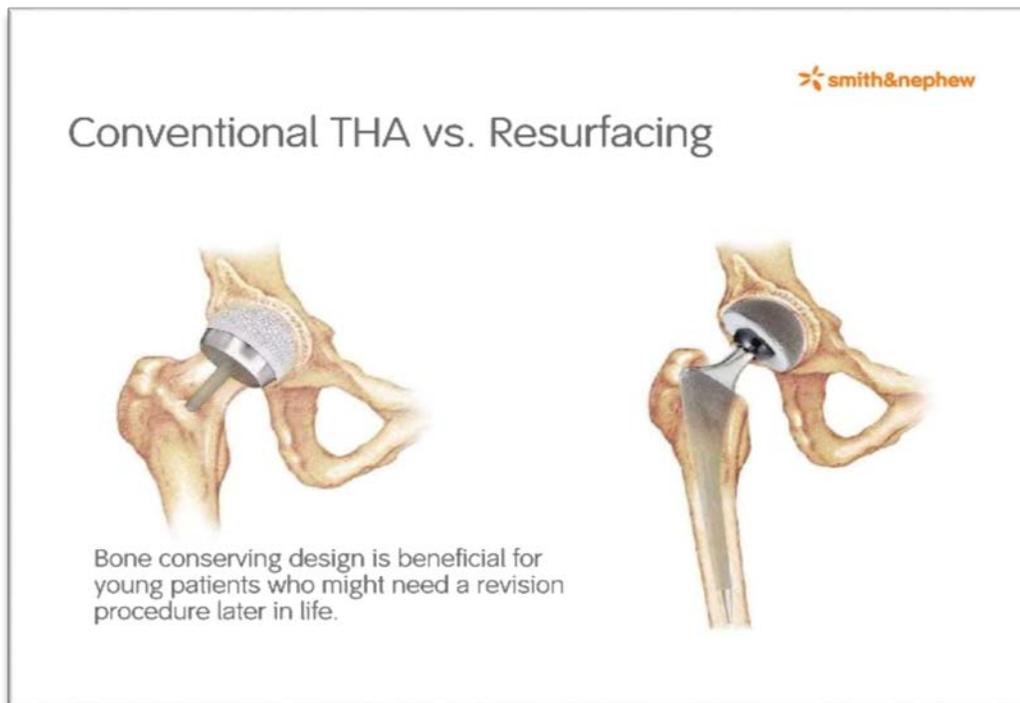
¹ The term, “approved” means the device reached the market through the premarket approval process in the Medical Device Amendments of 1976, 21 U.S.C. sec. 360c et seq and “cleared” means the FDA determined under 21 U.S.C. sec. 510(k) that the device was substantially equivalent to devices already on the market in 1976. *See generally, Medtronic v. Lohr*, 116 S. Ct. 2240 (1996); *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

implant MDLs have primarily involved a company's integrated product system that received FDA approval or clearance. The two devices already involved in MDL 2775 are as follows:

- *Birmingham Hip Resurfacing Device*: Commonly referred to by its abbreviation "BHR," this device is what is shown in the left hip in the illustration below. It is not considered a "traditional" total hip arthroplasty because it only resurfaces, or shaves down, the femoral head instead of replacing the entire femoral head and neck. It was FDA-approved under PMA number P040033 on May 9, 2006.
- *Modular Femoral (Hemi) Head and Modular Sleeve*: These two metal parts mated together and were sold and marketed in Europe and Australia as the main components of the Birmingham Hip Modular Head System. The head and sleeve were never cleared or approved for total hip arthroplasties, but this device was used almost exclusively in the U.S. off-label for that surgery.

A third product, the Smith & Nephew *R3 Acetabular System metal liner*, is likely to be included in the MDL soon. The metal liner was approved on November 13, 2008 as PMA supplement S006 to the BHR. The metal liner was never approved in the U.S. for use in traditional total hip arthroplasties, but the vast majority of them were used for that surgery. The analysis below does not change whether the liner is or is not included in the MDL, because the "modular femoral (hemi) head" is the same with or without the liner.

The illustration below from a Smith & Nephew Power Point depicts the difference between the two surgeries. The one on the left is the BHR and the one on the right is the THA.



The most notable difference is the large spike-like stem in the THA on the right.

For the first year of its existence, MDL 2775 was a single product affair, involving only the BHR hip resurfacing cases. The MDL Panel not only consolidated all the Birmingham Hip Resurfacing (BHR) cases into one MDL in early 2017, but the Panel also expressly declined to include S&N's Total Hip Arthroplasty ("THA") cases. This MDL remained a single product case until January 2018 when the MDL Panel began sending THA cases to Baltimore. It now involves the resurfacing and THA cases involving the BHR cup, and it will probably include the R3 Metal Liner cases before long. There are 318 cases currently in this MDL, according to the "Notice of Filing Updated Listings of Pending BHR Track and THA Track Cases" filed on May 21, 2018, with 264 described as "BHR" cases and 54 listed as "THA" cases. New cases are currently being filed in or transferred to this MDL almost every day.

- **REGULATORY SHENANIGANS.**

The regulatory history of the Smith & Nephew metal hip devices is unique in metal-on-metal hip litigation for at least two reasons. Unlike other hip implant MDLs, there is no FDA cleared total hip replacement or resurfacing *system* involved. There is no name for the configuration of THA implants involved in this MDL because the company was unable to obtain clearance for a metal on metal total hip implant system. The parties and the MDL Court just call them "THA cases", referring to the generic name for the *surgery* as opposed to an actual legally marketed *product*. The case is also unusual because the FDA expressly *rejected* the femoral part of the THA metal parts involved in this MDL. The company obviously knew this when it happened, but what they did about it is probably what got them into MDL 2775.

The FDA refused to allow Smith & Nephew to market their THA device *three separate times* from 2005 to 2010. Many of us have handled cases involving implantable devices that were FDA approved or FDA cleared, and some might have even handled cases involving hybrid devices that were part approved and part cleared. Issues of the prescribing doctor's off label use of the drug or device frequently permeate many of our pharmaceutical cases. But the Smith & Nephew metal on metal total hip arthroplasty cases always involve a rare four-part combination *in each surgery* of the following: (1) parts approved by the FDA's premarket approval process, (2) parts cleared by the FDA's premarket 510(k) notification process, (3) surgeon use of the parts in unapproved ways, *and* (4) parts that the FDA specifically refused to allow for sale in this country – three separate times. Sparks are going to fly whenever a case involves all these conflicting elements, and the Smith & Nephew total hip replacement cases will be no exception. The next section of this paper will briefly explain how all these facts have resulted in a remarkably troublesome case for Smith & Nephew. The Smith & Nephew THA cases will undoubtedly present unique factual and legal questions as they work their way through our court systems.

1. Numerous FDA "No Sell" Letters.

It goes without saying that you cannot properly analyze a products liability case without first determining how the offending product got on the road, in the air, in your home, or on hospital shelves. This is usually easy to determine, especially if the product was expressly approved by the governing body. Of course, in a regulated society the product is usually on the

market legally. In my experience, it is very rare to find a products liability case where the product itself was not even *allowed* on the market. But that's what we seem to have in the Smith & Nephew THA cases.

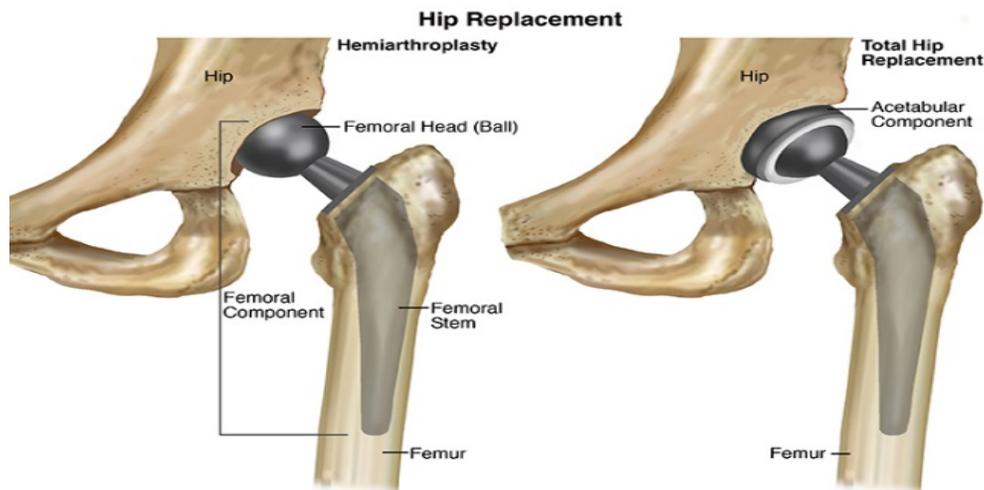
Starting as early as 2005, Smith & Nephew began efforts to gain FDA clearance for a traditional THA system in the U.S. Its first 510(k) application for this involved a product called the "Birmingham Hip Modular Head System." This application was filed on October 4, 2005. The FDA assigned it file number K052808. It was intended to be marketed both for primary (e.g. first) traditional hip arthroplasty procedures and as a revision option for failed BHRs. The FDA confirmed receipt of the premarket notification and included this written warning: "YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO." *Letter from FDA to Smith & Nephew*, at 1 (Oct. 4, 2005), *emphasis in original*. I call this a "No Sell" letter. All manufacturers understand that they cannot sell a product involved in FDA premarket notification activities unless and until the FDA issues a written determination allowing it².

Two months later, the FDA concluded that it was unable to determine that the Birmingham Hip Modular Head System was substantially equivalent to the predicate devices in the 510(k) application. The FDA explained that there was a lack of clinical data supporting the device, noting that it disagreed with Smith & Nephew's attempt to rely on BHR clinical data for its THA submission. The FDA further explained that "the clinical data for a resurfacing hip prosthesis can not be used to predict the safety and effectiveness of a total hip prosthesis." K052808. *Letter from FDA to Smith & Nephew*, at 1 (Dec. 12, 2005). The FDA basically rejected all the clinical data the company offered. The FDA even suggested that the application might be better suited as a supplement to the BHR. The FDA issued another No Sell letter. Smith & Nephew withdrew K052808 on March 1, 2006, and the FDA issued yet another No Sell letter.

Smith & Nephew had hit a THA dead-end with the FDA after failing to gain FDA clearance for the Birmingham Hip Modular Head System. It decided to approach the problem one component part at a time. On May 1, 2006, Smith & Nephew filed a 510(k) application for a "monoblock" femoral head. It was assigned 510(k) number K061243, and the FDA cleared the device on July 17, 2006, but only for use in hemi-arthroplasties. An application for the "Modular Femoral (Hemi) Head" was filed a month later, on August 17, 2006. (K062408) The FDA granted that application on September 12, 2006. These two applications for 510(k) premarket clearances were granted only for "hemiarthroplasty" procedures, where the metal femoral head articulates only against natural bone. Again, the metal femoral head used in the Smith & Nephew THA cases in MDL 2775 was never approved or cleared for THA procedures. A hemiarthroplasty can never be a metal on metal hip device, and none of the cases in the MDL should ever involve this procedure. This is important because every Smith & Nephew metal on metal THA case involves a femoral component that was only cleared for a hemiarthroplasty.

² Attached to this paper are a few of the No Sell letters for the very Smith & Nephew products involved in the "THA Track" of MDL 2775. These are just samples and there are more, but this will give you the idea.

The illustration below³ depicts the difference between a hemiarthroplasty and a total hip arthroplasty.



The most notable difference in the above illustrations is that the hemiarthroplasty does not have any artificial acetabular component.

Around this same time, on July 28, 2006, Smith & Nephew filed a *second* 510(k) application for the Birmingham Hip Modular Head System (K062189). Soon thereafter, the FDA issued a ten page No Sell letter and advised Smith & Nephew that it still couldn't determine whether the device was substantially equivalent to the predicate devices. The FDA's concerns with the clinical data for this application were similar to its concerns with the first application; the long list of deficiencies included criticisms about the investigative site's location and investigator, and noted that the study had no "clear patient inclusion/exclusion criteria." *Letter from FDA to Smith & Nephew re: FDA's K062189*, at 1 (Oct. 25, 2006). The FDA also found that there was a significant amount of missing data, *id.* at 2, and the FDA recommended that an application for this device for a THA should "be submitted as a PMA supplement" to the BHR. *Id.* at 9. Rather than curing the deficiencies in the No Sell letter, Smith & Nephew withdrew its 510(k) application on March 21, 2007, and the FDA issued yet another No Sell letter.

Smith & Nephew was not so quick to file its *third* 510(k) application for a THA system, waiting until after it launched its R3 Acetabular System and secured PMA approval for the R3 Metal Liner for use as part of the BHR. However, Smith & Nephew filed another 510(k) application for the Birmingham Hip Modular Head System on October 1, 2009 (K093095). Unsurprisingly, the FDA issued another lengthy No Sell letter and again told Smith & Nephew that it was unable to determine substantial equivalence. Like clockwork, Smith & Nephew withdrew its 510(k) application a few months later, on February 24, 2010. The FDA issued yet another No Sell letter.

³ Source: India Health Help, <http://Russian.indiahealthhelp.com/procedure/hip-arthroplasty/> (last visited May 22, 2018).

There were about a dozen No Sell letters issued for Smith & Nephew's THA metal on metal hip products eventually. Smith & Nephew stopped trying to obtain clearance for these components for use in total hip arthroplasties after their third failure. All of the No Sell letters involve the same femoral head that is in all the Smith & Nephew metal on metal THA cases. After years of trying and after collecting a dozen or so No Sell letters, Smith & Nephew abandoned its efforts to obtain FDA clearance or approval to sell the combination of metal parts used in its THA cases.

2. Sell Despite No Sell Letters.

It is important to emphasize that use of these devices for unapproved THA surgeries was not rare or isolated. The most frequent use for the modular femoral head was off-label as part of metal-on-metal total hip arthroplasties, usually articulating against either the R3 Metal Liner or an unlined BHR acetabular cup. That is how they are almost always used if they are used in a metal-on-metal THA. The company knew their THA product was not approved and had been expressly rejected three times by early 2010, but the company still distributed the parts for these uses. Unable to lawfully promote the parts for THA surgeries, they employed a business model similar to a politician engaging strictly in negative politics. Among other tactics, they employed a sales campaign known as "Take the Gloves Off," which allowed the sales reps to vigorously criticize the competition, but strictly prohibited them from saying anything positive about their own products.

It should not be surprising that Smith & Nephew's commission-based sales reps complained when they had to meet quotas but didn't have a full line of products they could sell their customers. Internal company documents show sales reps nationwide complaining and asking when they would finally be allowed to sell a metal-on-metal THA product. Some hospitals wouldn't even discuss THA implants with the Smith & Nephew sales reps due to lack of FDA cleared hip devices. The pressure on sales reps to quietly promote the hemiarthroplasty head for unapproved THA surgeries was enormous. I know of at least two surgeons who have testified that the Smith & Nephew sales reps did exactly that.

An integral part of Smith & Nephew's sales campaign also involved keeping the foregoing regulatory history from the doctors and sales reps. Smith & Nephew usually did not inform surgeons and sales reps of this dubious regulatory history. You will probably never meet a surgeon or sales rep who admits they knew these regulatory facts at the time a Smith & Nephew THA surgery occurred. Smith & Nephew, Inc. executives in Memphis, Tennessee and at the home office in the United Kingdom knew these facts. The doctors and sales reps did not know them. Of course, the patients did not know either.

3. FDA Reclassification of Metal Hip Implants.

An implanting surgeon in one of my Smith & Nephew cases testified that the metal on metal hip situation in America was a "human experiment." It was a failed experiment by all accounts, but Smith & Nephew wasn't even allowed to participate in this failed "experiment."

According to the FDA's website⁴, "as of Nov. 30, 2012, the FDA had cleared 190 submissions for metal-on-metal hip replacement systems." The FDA could probably be criticized for allowing so many metal on metal hip systems to easily slip through its regulatory system, but no one can say they let Smith & Nephew slip by. The FDA did what they could to stop Smith & Nephew, but it wasn't enough, and that's why there's a new "THA Track" for the Smith & Nephew MDL.

CONCLUSION

The metal liner that will probably soon be involved in the Smith & Nephew MDL was recalled from the U.S. market for safety reasons in 2012 and the modular femoral head already in the MDL was withdrawn for safety reasons in 2015. The FDA issued more than a dozen No Sell letters in response to Smith & Nephew's repeated efforts over four + years to secure clearance to market a metal-on-metal THA hip product in this country. They probably thought they had stopped Smith & Nephew with all their No Sell letters over the years, but the existence of 50 + THA cases already on file in MDL 2775 suggests otherwise.

All of the documents referenced in this paper are available on my website: www.KipPetroff.com. You can also email me at kpetroff@petroffassociates.com or call me at (972) 294-7530 with any questions. As usual, I'm sharing all this information for free at my website.

Sincerely yours,

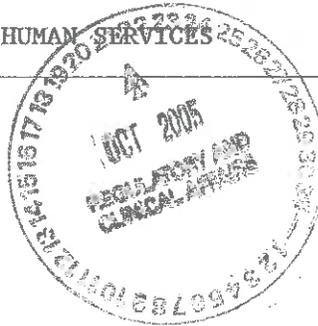
Kip A. Petroff

⁴ U.S. Food & Drug Administration, Metal-on-Metal Hip Implant Systems, <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241601.htm> (Dec. 28, 2017).

Attachments to Kip Petroff's Paper Re:
Smith & Nephew MDL

FDA "No Sell" Letters

October 06, 2005



Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

SMITH & NEPHEW, INC.
ORTHOPAEDIC DIVISION
1450 BROOKS RD.
MEMPHIS, TN 38116
ATTN: GINO J. ROUSS

510(k) Number: K052808
Received: 05-OCT-2005
Product: BIRMINGHAM HIP (BH)
MODULAR HIP SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/oivd/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

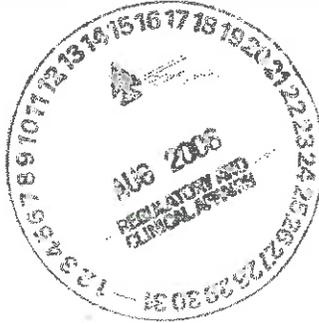
You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,
Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation



August 01, 2006



Food and Drug Administration
 Center for Devices and
 Radiological Health
 Office of Device Evaluation
 Document Mail Center (HFZ-401)
 9200 Corporate Blvd.
 Rockville, Maryland 20850

SMITH & NEPHEW, INC.
 ORTHOPAEDIC DIVISION
 1450 BROOKS RD.
 MEMPHIS, TN 38116
 ATTN: GINO ROUSS

510(k) Number: K062189
 Received: 31-JUL-2006
 Product: BIRMINGHAM HIP (BH)
 MODULAR HIP SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review:
 1) Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html.
 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).
 3) Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's eCopy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.



RAAB-0025534

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0062

October 05, 2009

SMITH & NEPHEW, INC.
ORTHOPAEDICS-RECONSTRUCTION & TRAUMA DIVISION
1450 BROOKS RD.
MEMPHIS, TENNESSEE 38116
UNITED STATES
ATTN: GINO J. ROUSS

510k Number: K093095

Received: 10/1/2009

Product: BIRMINGHAM HIP (BH) MODULAR HE

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological



RAAB-0024369

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, “Format for Traditional and Abbreviated 510(k)s”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff