

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Food and Drug Administration

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Expiration Date: 3/31/02

**CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS**

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigator	(See attached list)	

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME <i>T. L. Craig</i>	TITLE <i>President</i>
FIRM/ORGANIZATION <i>OSMA</i>	
SIGNATURE <i>[Signature]</i>	DATE <i>5/15/01</i>

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right.

Department of Health and Human Services  
Food and Drug Administration  
5600 Fishers Lane, Room 14C-03  
Rockville, MD 20857

## Study A Investigator List

Investigator	Investigational Site
David Mattingly, MD	New England Baptist Hospital 125 Parker Hill Road Boston, MA 02120
Steven M. Teeny, MD	Lakewood Orthopaedic Surgeons, PS 5605 100 <sup>th</sup> Street SW Tacoma, WA 98499-2744
Douglas Dennis, MD	Colorado Joint Replacement 2425 S. Colorado Blvd., Suite 270 Denver, CO 80222
Robert Gorab, MD	OSMG, Inc. 1140 West LaVeta, Suite 850 Orange, CA 92868
Michael Jacobs, MD	Good Samaritan Hospital Russell Morgan Building, Suite 405 5601 Loch Raven Boulevard Baltimore, MD 21239
Lorence W. Trick, MD	Orthopaedic Surgery Associates 414 Navarro, Suite 1128 San Antonio, TX 78205
Richard Schubert, MD	W.B. Carrell Memorial Clinic Assoc. 2909 Lemmon Avenue Dallas, TX 75204
Michael L. Swank, M.D.	Freiberg Spine Institute 4760 E Galbraith Road Suite 109 Cincinnati, OH 45236
Thomas B. Volatile, MD	Delmarva Orthopaedic Clinic 510 Idlewild Avenue Easton, MD 21601-3824
Harry E Jergesen, MD	University of California, San Francisco Department of Orthopaedic Surgery 500 Parnassus Avenue MU320W San Francisco, CA 94143-0728
Bertram Kwasman, M.D.	Carl T. Hayden VA Medical Center Department of Orthopaedic Surgery 650 East Indian School Road Phoenix, AZ 85012
Christopher P. Beauchamp, M.D.	Mayo Clinic Scottsdale 13400 East Shea Boulevard Scottsdale, AZ 85259-5404

## Study B

### Investigator List

Investigator	Investigational Site
1) Mr M S Bhamra, ChM, FRCS, Consultant Orthopaedic Surgeon	Rotherham District General Hospital Moorgate Road Rotherham South Yorkshire S60 2UD
2) Mr J F Nolan, FRCS (Ortho.), Consultant Orthopaedic Surgeon 3) Mr H Phillips, FRCS Consultant Orthopaedic Surgeons 4) Mr J K Tucker, FRCS Consultant Orthopaedic Surgeon	Norfolk & Norwich Hospital NHS Trust Brunswick Road Norwich Norfolk NR1 3SR
5) Mr R N Villar, MS, FRCS, Consultant Orthopaedic Surgeon	Cambridge Hip and Knee Unit Cambridge Lea Hospital 30 New Road Impington Cambridge Cams. CB4 4EL

## Study C Investigator List

Investigator	Investigational Site
1) Thomas Mallory, M.D.	720 E. Broad Street Columbus, Ohio 43205
2) Adolph Lombardi, M.D.	720 E. Broad Street Columbus, Ohio 43205
3) E. Micheal Keating, M.D.	Center for Hip & Knee Surgery 1199 Hadley Road Mooreville, Indiana 46158
4) Merrill A. Ritter, M.D.	Center for Hip & Knee Surgery 1199 Hadley Road Mooreville, Indiana 46158
5) Philip M. Faris, M.D.	Center for Hip & Knee Surgery 1199 Hadley Road Mooreville, Indiana 46158
6) Carl Nelson, M.D.	4301 W. Markham Street, Slot 644 Little Rock, Arkansas 72205
7) Michael Alexiades, M.D.	159 E. 74 <sup>th</sup> Street New York, New York 10021
8) Chitranjan Ranawat, M.D.	130 E. 77 <sup>th</sup> Street 11 <sup>th</sup> Floor William-Black Hall New York, New York 10021
9) Richard Wixson, M.D.	676 N. St. Clair Suite 450 Chicago, Illinois 60611
10) Joseph Williams, M.D.	621 S. New Ballas Road, Suite 101 St. Louis, Missouri 63141
11) John Cuckler, M.D.	University of Alabama at Birmingham 508 Medical Education Building 1813 Sixth Avenue Birmingham, Alabama 35294-3295
12) Kenneth Jaffe, M.D.	University of Alabama at Birmingham 508 Medical Education Building 1813 Sixth Avenue Birmingham, Alabama 35294-3295