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PTO/SB/05 (4/98)
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	97012CIP
First Inventor or Application Identifier	DiGioia
Title	COMPUTER-ASSISTED SURGERY PLANNER
Express Mail Label No.	EJ273550494US

11/12/98
JCS51 U.S. PTO

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

- * Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
- Specification [Total Pages (preferred arrangement set forth below)
 - Descriptive title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
- Drawing(s) (35 U.S.C. 113) [Total Sheets - Oath or Declaration [Total Pages - Newly executed (original or copy)
- Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 16 completed)
 - DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

- Microfiche Computer Program (Appendix)
- Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - Computer Readable Copy
 - Paper Copy (identical to computer copy)
 - Statement verifying identity of above copies

- ### ACCOMPANYING APPLICATION PARTS
- Assignment Papers (cover sheet & document(s))
 - 37 C.F.R. § 3.73(b) Statement Power of Attorney
(when there is an assignee)
 - English Translation Document (if applicable)
 - Information Disclosure Statement (IDS)/PTO-1449 Copies of IDS Citations
 - Preliminary Amendment
 - Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
 - * Small Entity Statement(s) Statement filed in prior application, Status still proper and desired (PTO/SB/09-12)
 - Certified Copy of Priority Document(s) (if foreign priority is claimed)
 - Other:

* NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:
 Continuation Divisional Continuation-in-part (CIP) of prior application No: 08 803,993
 Prior application information: Examiner R. Freid Group / Art Unit: 2763
 For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

Customer Number or Bar Code Label Correspondence address below
 (Insert Customer No. or Attach bar code label here)

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Name (Print/Type)	Jonathan C. Parks	Registration No. (Attorney/Agent)	40,120
Signature		Date	11/12/98

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<h2 style="text-align: center;">FEE TRANSMITTAL</h2> <p style="text-align: center;"><i>Patent fees are subject to annual revision on October 1. These are the fees effective October 1, 1997. Small Entity payments <u>must</u> be supported by a small entity statement, otherwise large entity fees must be paid. See Forms PTO/SB/09-12. See 37 C.F.R. §§ 1.27 and 1.28.</i></p>	Complete if Known	
	Application Number	
	Filing Date	
	First Named Inventor Anthony M. DiGioia	
	Examiner Name	
	Group / Art Unit	
TOTAL AMOUNT OF PAYMENT	(\$) 1,562.00	
Attorney Docket No.		97012CIP

<p>METHOD OF PAYMENT (check one)</p> <p>1. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge indicated fees and credit any over payments to: Deposit Account Number 11-1110 Deposit Account Name Kirkpatrick & Lockhart LLP <input checked="" type="checkbox"/> Charge Any Additional Fee Required Under 37 CFR §§ 1.16 and 1.17 <input type="checkbox"/> Charge the Issue Fee Set in 37 CFR § 1.18 at the Mailing of the Notice of Allowance</p> <p>2. <input checked="" type="checkbox"/> Payment Enclosed: <input checked="" type="checkbox"/> Check <input type="checkbox"/> Money Order <input type="checkbox"/> Other</p> <p style="text-align: center;">FEE CALCULATION</p> <p>1. BASIC FILING FEE</p> <table style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Large Entity Fee Code (\$)</th> <th>Small Entity Fee Code (\$)</th> <th>Fee Description</th> <th>Fee Paid</th> </tr> </thead> <tbody> <tr> <td>101 790</td> <td>201 395</td> <td>Utility filing fee</td> <td style="text-align: center;">790.</td> </tr> <tr> <td>106 330</td> <td>206 165</td> <td>Design filing fee</td> <td></td> </tr> <tr> <td>107 540</td> <td>207 270</td> <td>Plant filing fee</td> <td></td> </tr> <tr> <td>108 790</td> <td>208 395</td> <td>Reissue filing fee</td> <td></td> </tr> <tr> <td>114 150</td> <td>214 75</td> <td>Provisional filing fee</td> <td></td> </tr> <tr> <td colspan="3" style="text-align: right;">SUBTOTAL (1)</td> <td style="text-align: center;">(\$) 790.00</td> </tr> </tbody> </table> <p>2. 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SUBMITTED BY		Complete (if applicable)	
Typed or Printed Name	Jonathan C. Parks	Reg. Number	40,120
Signature		Date	11/12/98
		Deposit Account User ID	

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TITLE OF THE INVENTION

Computer-Assisted Surgery Planner and Intra-Operative
Guidance System

5 CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part application
of application Serial Number 08/803,993, filed February 21,
1997.

10 STATEMENT REGARDING FEDERALLY SPONSORED
RESEARCH OR DEVELOPMENT

This work was supported in part by a National Challenge
grant from the National Science Foundation Award IRI 9422734.

15 BACKGROUND OF THE INVENTION

The present invention is directed generally to the
implantation of artificial joint components, osteochondral
grafts, and osteotomy and, more particularly, to computer
20 assisted surgical implantation of artificial joint components
during replacement and revision procedures, computer-assisted
osteochondral grafts, and computer-assisted osteotomy.

Total hip replacement (THR) or arthroplasty (THA)
operations have been performed since the early 1960s to
25 repair the acetabulum and the region surrounding it and to
replace the hip components, such as the femoral head, that
have degenerated. Currently, approximately 200,000 THR
operations are performed annually in the United States alone,
of which approximately 40,000 are redo procedures, otherwise
30 known as revisions. The revisions become necessary due to a
number of problems that may arise during the lifetime of the
implanted components, such as dislocation, component wear and
degradation, and loosening of the implant from the bone.

Dislocation of the femoral head from the acetabular
35 component, or cup, is considered one of the most frequent

early problems associated with THR, because of the sudden physical, and emotional, hardship brought on by the dislocation. The incidence of dislocation following the primary THR surgery is approximately 2-6% and the percentage is even higher for revisions. While dislocations can result from a variety of causes, such as soft tissue laxity and loosening of the implant, the most common cause is impingement of the femoral neck with either the rim of an acetabular cup implant, or the soft tissue or bone surrounding the implant. Impingement most frequently occurs as a result of the malposition of the acetabular cup component within the pelvis.

Some clinicians and researchers have found incidence of impingement and dislocations can be lessened if the cup is oriented specifically to provide for approximately 15° of anteversion and 45° of abduction; however, this incidence is also related to the surgical approach. For example, McCollum et al. cited a comparison of THAs reported in the orthopaedic literature that revealed a much higher incidence of dislocation in patients who had THAs with a posterolateral approach. McCollum, D.E. and W.J. Gray, "Dislocation after total hip arthroplasty (causes and prevention)", Clinical Orthopaedics and Related Research, Vol. 261, p.159-170 (1990). McCollum's data showed that when the patient is placed in the lateral position for a posterolateral THA approach, the lumbar lordotic curve is flattened and the pelvis may be flexed as much as 35°. If the cup was oriented at 15-20° of flexion with respect to the longitudinal axis of the body, when the patient stood up and the postoperative lumbar lordosis was regained, the cup could be retroverted as much as 10°-15° resulting in an unstable cup placement. Lewinnek et al. performed a study taking into account the surgical approach utilized and found that the cases falling in the zone of 15°±10° of anteversion and 40°±10° of abduction have an instability rate of 1.5%, compared with a 6% instability rate for the cases falling outside this zone.

Lewinnek G.E., et al., "Dislocation after total hip-replacement arthroplasties", Journal of Bone and Joint Surgery, Vol. 60-A, No.2, p. 217-220 (March 1978). The Lewinnek work essentially verifies that dislocations can be correlated with the extent of malpositioning, as would be expected. The study does not address other variables, such as implant design and the anatomy of the individual, both of which are known to greatly affect the performance of the implant.

10 The design of the implant significantly affects stability as well. A number of researchers have found that the head-to-neck ratio of the femoral component is the key factor of the implant impingement, see Amstutz H.C., et al., "Range of Motion Studies for Total Hip Replacements", Clinical Orthopaedics and Related Research Vol. 111, p. 124-130 (September 1975). Krushell et al. additionally found that certain long and extra long neck designs of modular implants can have an adverse effect on the range of motion. Krushell, R.J., Burke D.W., and Harris W.H., "Range of motion in contemporary total hip arthroplasty (the impact of modular head-neck components)", The Journal of Arthroplasty, Vol. 6, p. 97-101 (February 1991). Krushell et al. also found that an optimally oriented elevated-rim liner in an acetabular cup implant may improve the joint stability with respect to implant impingement. Krushell, R.J., Burke D.W., and Harris W.H., "Elevated-rim acetabular components: Effect on range of motion and stability in total hip arthroplasty", The Journal of Arthroplasty, Vol. 6 Supplement, p. 1-6, (October 1991). Cobb et al. have shown a statistically significant reduction of dislocations in the case of elevated-rim liners, compared to standard liners. Cobb T.K., Morrey B.F., Ilstrup D.M., "The elevated-rim acetabular liner in total hip arthroplasty: Relationship to postoperative dislocation", Journal of Bone and Joint Surgery, Vol 78-A, No. 1, p. 80-86, (January 1996). The two-year probability of dislocation was 2.19% for the elevated liner, compared with 3.85% for standard liner.

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